NICE National Institute for Health and Care Excellence

NICE guideline

Early and locally advanced breast cancer: diagnosis and management

NICE guideline

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Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guideline replaces CG80, TA107, TA108, TA109 and TA112.

This guideline is the basis of QS12.

Overview

This guideline covers diagnosing and managing early and locally advanced breast cancer. It aims to help healthcare professionals offer the right treatments to people, taking into account the person's individual preferences. NICE has also produced guidelines on advanced breast cancer, familial breast cancer and suspected cancer recognition and referral.

Who is it for?

- Healthcare professionals
- Commissioners and providers of breast cancer services
- People with early and locally advanced breast cancer, their families and carers

Recommendations

People have the right to be involved in discussions and make informed decisions about their care, as described in your care.

Breast cancer affects women and men, and can affect those who have undergone a gender reassignment or who are non-binary. We have used the term 'women' in this guideline for recommendations that usually only relate to women (such as breast-conserving surgery) and 'people' in all other cases. However, no discrimination is intended and recommendations relate to all those who have early or locally advanced breast cancer.

Making decisions using NICE guidelines explains how we use words to show the strength (or certainty) of our recommendations, for example, we use 'offer' to reflect a strong recommendation, usually where there is clear evidence of benefit and we use 'consider' to reflect a recommendation for which the evidence of benefit is less certain. There is also information about prescribing medicines (including off-label use), professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.

1.1 Referral, diagnosis and preoperative assessment

Preoperative assessment of the breast and axilla

1.1.1 Do not routinely use MRI of the breast in the preoperative assessment of people with biopsy-proven invasive breast cancer or ductal carcinoma in situ (DCIS). [2009]

1.1.2 Offer MRI of the breast to people with invasive breast cancer:

- if there is discrepancy regarding the extent of disease from clinical examination, mammography and ultrasound assessment for planning treatment
- if breast density precludes accurate mammographic assessment
- to assess the tumour size if breast-conserving surgery is being considered for invasive lobular cancer. [2009]

Preoperative staging of the axilla

1.1.3 Perform pretreatment ultrasound evaluation of the axilla for people having investigations for early invasive breast cancer and, if abnormal lymph nodes are identified, perform ultrasound-guided needle sampling. [2009]

Genetic testing

1.1.4 Offer genetic testing for BRCA1 and BRCA2 mutations to women under 50 years with triple-negative breast cancer, including those with no family history of breast or ovarian cancer. (Also see genetic testing in the NICE guideline on familial breast cancer.) **[2017, amended 2018]**

1.2 Providing information and psychological support

1.2.1 All members of the breast cancer clinical team should follow the recommendations on communication in NICE's guideline on patient experience in adult NHS services. **[2009, amended 2018]**

1.2.2 All people with breast cancer should have a named clinical nurse specialist or other specialist key worker with equivalent skills, who will support them throughout diagnosis, treatment and follow-up. **[2009, amended 2018]**

1.2.3 Offer all people with breast cancer prompt access to specialist psychological support and, where appropriate, psychiatric services. **[2009]**

1.2.4 Discuss opportunities for people with breast cancer to be involved in research, and encourage entry into clinical trials and other studies. **[2018]**

> To find out why the committee made the 2018 recommendation on involvement in research and how it might affect practice, see rationale and impact.

1.2.5 For guidance on fertility preservation, see the section on people with cancer who wish to preserve fertility in the NICE guideline on fertility problems. **[2018]**

> To find out why the committee made the 2018 recommendation on fertility preservation and how it might affect practice, see rationale and impact.

1.3 Surgery to the breast

1.3.1 Offer further surgery (re-excision or mastectomy, as appropriate) after breast-conserving surgery where invasive cancer and/or DCIS is present at the radial margins ('tumour on ink'; 0 mm). **[2018]**

1.3.2 For women who have had breast-conserving surgery where invasive cancer and/or DCIS is present within 2 mm of, but not at, the radial margins (greater than 0 mm and less than 2 mm):

- discuss the benefits and risks of further surgery (re-excision or mastectomy) to minimise the risk of local recurrence
- take into account the woman's preferences, comorbidities, tumour characteristics and the potential use of radiotherapy (also see radiotherapy after breast-conserving surgery). **[2018]**

> To find out why the committee made the 2018 recommendations on surgery to the breast and how they might affect practice, see rationale and impact.

1.3.3 All breast units should audit their recurrence rates after treatment. **[2009, amended 2018]**

Paget's disease

1.3.4 Offer breast-conserving surgery with removal of the nipple–areolar complex as an alternative to mastectomy for people with Paget's disease of the nipple that has been assessed as localised. Offer oncoplastic repair techniques to maximise cosmesis. **[2009]**

1.4 Surgery to the axilla

Invasive breast cancer

1.4.1 Perform minimal surgery, rather than lymph node clearance, to stage the axilla for people with invasive breast cancer and no evidence of lymph node involvement on ultrasound or a negative ultrasound-guided needle biopsy. Sentinel lymph node biopsy (SLNB) is the preferred technique. **[2009]**

1.4.2 Perform SLNB using the dual technique with isotope and blue dye. **[2009]**

1.4.3 Breast units should audit their axillary recurrence rates. **[2009]**

Ductal carcinoma in situ

1.4.4 Do not perform SLNB routinely for women with a preoperative diagnosis of DCIS who are having breast-conserving surgery, unless they are considered to be at high risk[1] of invasive disease. People at high risk of invasive disease include those with a palpable mass or extensive microcalcifications. **[2009]**

1.4.5 Offer SLNB to all people who are having a mastectomy for DCIS. **[2009]**

Evaluation and management of a positive axillary lymph node identified by a preoperative ultrasound-guided needle biopsy

1.4.6 Offer axillary node clearance to people with invasive breast cancer who have a preoperative ultrasound-guided needle biopsy with pathologically proven lymph node metastases. **[2009, amended 2018]**

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)

1.4.7 Offer further axillary treatment (axillary node clearance or radiotherapy) after SLNB to people who have 1 or more sentinel lymph node macrometastases. **[2018]**

1.4.8 Discuss the benefits and risks of having no further axillary treatment after primary breast-conserving surgery (within clinical trials where available) with women who:

- have 1 or 2 sentinel lymph node macrometastases **and**
- have been advised to have whole-breast radiotherapy with systemic therapy (which may be endocrine therapy). **[2018]**

1.4.9 Do not offer further axillary treatment after primary surgery to people with invasive breast cancer who have only micrometastases in their sentinel lymph nodes. **[2018]**

1.4.10 Do not offer further axillary treatment after primary surgery to people with invasive breast cancer who have only isolated tumour cells in their sentinel lymph nodes. Regard these people as having lymph node-negative breast cancer.

[2018]

> To find out why the committee made the 2018 recommendations on evaluation and management of a positive axillary lymph node, and how they might affect practice, see rationale and impact.

1.5 Breast reconstruction

1.5.1 Offer both breast reconstruction options to women (immediate reconstruction and delayed reconstruction), whether or not they are available locally. [2018]

1.5.2 Be aware that some women may prefer not to have breast reconstruction surgery. [2018]

1.5.3 Offer immediate breast reconstruction to women who have been advised to have a mastectomy, including those who may need radiotherapy, unless they have significant comorbidities that rule out reconstructive surgery. [2018]

1.5.4 Discuss the benefits and risks of immediate breast reconstruction and delayed breast reconstruction with women. Topics to discuss include those in table 1 and:

- the timing of breast reconstruction surgery (at the same time as mastectomy or later)
- different breast reconstruction surgery options and what they involve
- how the timing of breast reconstruction surgery affects the options available
- the uncertainty over long-term outcomes in women having radiotherapy. [2018]

Table 1 Breast reconstruction options for women who choose breast reconstruction

	Immediate breast reconstruction	Delayed breast reconstruction
Definition	Reconstruction is started in the same operation as the mastectomy.	After a mastectomy, reconstruction is done in a separate operation.

<table>
<tr><td>Number and timing of operations</td><td colspan="2">For both types, more than 1 operation is usually needed to complete the reconstruction.
The total number of operations will vary. It may be affected by factors such as:
type of reconstruction (for example, some are planned in stages; a prosthesis may be worn until reconstruction is complete)
personal preferences (such as whether a nipple reconstruction is requested).</td></tr>
<tr><td></td><td>Fewer operations may be needed.</td><td>More operations may be needed.</td></tr>
<tr><td>Breast reconstruction options available</td><td colspan="2">These will vary depending on personal preferences (such as breast size desired), current body shape, other health conditions, previous operations and lifestyle factors (such as hobbies).
Not all hospitals or surgeons can offer all procedures. Travel to a different hospital may be needed for a specific option.</td></tr>
<tr><td></td><td>Options may be available that spare or preserve the breast skin (which may mean less scarring and a more natural look).
Limited time to make a decision about options (which may include not having a reconstruction) before surgery.</td><td>Certain options that spare or preserve the breast skin may not be available.
More time to make a decision (which may include not having a reconstruction) and to plan reconstruction.</td></tr>
<tr><td>Benefits</td><td>Breast shape remains, which may have psychological benefits.</td><td>Lifestyle changes (such as losing weight and taking regular exercise) may be possible, which increase the options and lower the risks of reconstruction surgery.
Procedures (and associated recovery) can be planned around other commitments.</td></tr>
<tr><td>Risks</td><td colspan="2">Surgical complications can occur after any breast reconstruction and will vary by type of procedure and personal risk factors.</td></tr>
</table>

	May be lower rates of: • tissue breakdown • surgery for flap removal if it cannot be used because of a complication (which may lead to delayed reconstruction and flat appearance for a period of time) • procedures to improve symmetry. Complications from the mastectomy or axillary surgery can occur during the recovery period.	May be lower rates of: • mastectomy site complications • flap or implant failure (which may lead to delayed reconstruction and flat appearance for a period of time) • capsular contracture (a scar layer around the implant that may lead to pain if severe). May need to interrupt hormone therapies (tamoxifen) for further surgery.
Satisfaction	No clear differences in satisfaction with completed reconstructions.	
Reconstruction and adjuvant therapy (including radiotherapy and chemotherapy)	Radiotherapy or chemotherapy can be given but may be delayed if there are complications from the mastectomy or reconstruction. Immediate reconstructions using implants may be more affected by radiotherapy than immediate flap reconstructions. May need adaptions to scans if a tissue expander is used. For example, may not be able to have MRI scans and may need modified radiotherapy planning.	Complications can also occur after mastectomy alone, which may delay chemotherapy or radiotherapy.

To find out why the committee made the 2018 recommendations on breast reconstruction and how they might affect practice, see rationale and impact.

1.6 Diagnostic assessment and adjuvant therapy planning

Predictive factors

1.6.1 Request the oestrogen receptor (ER), progesterone receptor (PR) and human epidermal growth receptor 2 (HER2) status of all invasive breast cancers simultaneously at the time of initial histopathological diagnosis. **[2018]**

1.6.2 Assess the ER status of all invasive breast cancers using standardised and quality-assured immunohistochemical techniques, and report the results quantitatively. **[2009]**

1.6.3 Assess the PR status of all invasive breast cancers using standardised and quality-assured immunohistochemical techniques, and report the results quantitatively. **[2018]**

1.6.4 Assess the HER2 status of all invasive breast cancers using standardised and quality-assured techniques, and report the results quantitatively. **[2009]**

1.6.5 Ensure that the ER, PR and HER2 statuses are available and recorded at the preoperative and postoperative multidisciplinary team meetings when systemic treatment is discussed. **[2018]**

> To find out why the committee made the 2018 recommendations on predictive factors and how they might affect practice, see rationale and impact.

Adjuvant therapy planning

1.6.6 Consider adjuvant therapy after surgery for people with invasive breast cancer, and ensure that recommendations are recorded at the multidisciplinary team meeting. **[2009]**

1.6.7 Base recommendations about adjuvant therapy on multidisciplinary team assessment of the prognostic and predictive factors, and the possible risks and benefits of the treatment. Make decisions with the person after discussing these factors. **[2009, amended 2018]**

1.6.8 Use the PREDICT tool to estimate prognosis and the absolute benefits of

adjuvant therapy for women with invasive breast cancer. **[2018]**

1.6.9 When using version 2.0 of the PREDICT tool[2], be aware that:

- it is less accurate for:
  - women under 30 with ER-positive breast cancer
  - women aged 70 and over
  - women with tumours larger than 50 mm
- it has not been validated in men **and**
- the validation may have under-represented some ethnic groups. **[2018]**

To find out why the committee made the 2018 recommendations on adjuvant therapy planning and how they might affect practice, see rationale and impact.

Tumour profiling tests to guide adjuvant chemotherapy decisions

The updated NICE guidance on tumour profiling tests will cover gene expression profiling and expanded immunohistochemistry tests to guide adjuvant chemotherapy decisions. The guidance is due to be published in October 2018.

1.7 Endocrine therapy

1.7.1 Treat people with invasive breast cancer, irrespective of age, with surgery and appropriate systemic therapy, rather than endocrine therapy alone, unless significant comorbidity precludes surgery. **[2009]**

Adjuvant endocrine therapy for invasive breast cancer

1.7.2 Offer tamoxifen as the initial adjuvant endocrine therapy for men and premenopausal women with ER-positive invasive breast cancer. **[2009, amended 2018]**

1.7.3 Offer an aromatase inhibitor[3] as the initial adjuvant endocrine therapy for postmenopausal women with ER-positive invasive breast cancer who are at medium or high risk[1] of disease recurrence. Offer tamoxifen to women who are

at low risk[1] of disease recurrence, or if aromatase inhibitors are not tolerated or are contraindicated. **[2009, amended 2018]**

Ovarian function suppression

1.7.4 Consider ovarian function suppression in addition to endocrine therapy for premenopausal women with ER-positive invasive breast cancer. **[2018]**

1.7.5 Discuss the benefits and risks of ovarian function suppression in addition to endocrine therapy with premenopausal women with ER-positive invasive breast cancer. Explain to women that ovarian function suppression may be most beneficial for those women who are at sufficient risk of disease recurrence to have been offered chemotherapy. **[2018]**

> To find out why the committee made the 2018 recommendations on ovarian function suppression and how they might affect practice, see rationale and impact.

Extended endocrine therapy

1.7.6 Offer extended therapy (total duration of endocrine therapy of more than 5 years) with an aromatase inhibitor[4] for postmenopausal women with ER-positive invasive breast cancer who are at medium or high risk[5] of disease recurrence and who have been taking tamoxifen for 2 to 5 years. **[2018]**

1.7.7 Consider extended therapy (total duration of endocrine therapy of more than 5 years) with an aromatase inhibitor[4] for postmenopausal women with ER-positive invasive breast cancer who are at low risk[5] of disease recurrence and who have been taking tamoxifen for 2 to 5 years. **[2018]**

1.7.8 Consider extending the duration of tamoxifen therapy for longer than 5 years for both premenopausal and postmenopausal women with ER-positive invasive breast cancer. **[2018]**

1.7.9 Discuss the benefits and risks of extended endocrine therapy with women. Topics to discuss include those in table 2. **[2018]**

Table 2 Effects of extended endocrine therapy

	Extended tamoxifen therapy (after an initial 5 years of tamoxifen therapy)	Extended endocrine therapy with an aromatase inhibitor (after 5 years of tamoxifen therapy)
Definition	Continuing to take tamoxifen after 5 years of tamoxifen therapy.	Switching to an aromatase inhibitor after 5 years of tamoxifen therapy.
Who can take this therapy	Premenopausal or postmenopausal women with ER-positive invasive breast cancer.	Postmenopausal women with ER-positive invasive breast cancer.
Effect on breast cancer recurrence *NOTE: The benefit for an individual person will depend on the risk of their cancer returning. For people with a low risk of recurrence, the benefits may not outweigh the risks or side effects.* *Medium or high risk may include people who have lymph node-positive breast cancer, with tumours that are T2 or greater and higher grade. Low risk may include people with lymph node-negative breast cancer, with smaller or lower-grade tumours.*	Lower rates of breast cancer recurrence compared with 5 years of tamoxifen therapy.	Lower rates of breast cancer recurrence compared with 5 years of tamoxifen therapy. In postmenopausal women, switching to an aromatase inhibitor may be more effective at reducing recurrence than continuing with tamoxifen.

Side effects *NOTE: These are common side effects experienced during additional years taking endocrine therapy. Most effects are reversible when tablets are stopped.*	Side effects of endocrine therapy will continue for additional years (for example, menopausal symptoms such as hot flushes). With extended use of tamoxifen: increased risk of thrombosis and endometrial cancer, and possibly bone density loss in premenopausal women.	Side effects of endocrine therapy will continue for additional years (for example, menopausal symptoms such as hot flushes). With extended use of aromatase inhibitors: bone density loss, and joint and muscle pain.
Fertility and family planning	Effects on fertility and family planning will continue for additional years as women should not become pregnant while taking tamoxifen, or within 2 months of stopping, because it may have adverse effects on the baby.	Not applicable as postmenopausal women only.

To find out why the committee made the 2018 recommendations on extended endocrine therapy and how they might affect practice, see rationale and impact.

Endocrine therapy for ductal carcinoma in situ

1.7.10 Offer endocrine therapy after breast-conserving surgery for women with ER-positive DCIS if radiotherapy is recommended but not received. **[2018]**

1.7.11 Consider endocrine therapy after breast-conserving surgery for women with ER-positive DCIS if radiotherapy is not recommended. **[2018]**

1.7.12 Discuss the benefits and risks of endocrine therapy after breast-conserving surgery for women with ER-positive DCIS. Topics to discuss include those in table 3. **[2018]**

Table 3 Effects of endocrine therapy after breast-conserving surgery for women with

ER-positive DCIS

	Endocrine therapy after breast-conserving surgery for women with ER-positive DCIS
Definition	Tamoxifen or an aromatase inhibitor for 5 years. Taken as a once-daily tablet.
Effect on survival and disease recurrence *NOTE: The benefit for an individual person will depend on the risk of their cancer returning. For people with low risk of recurrence, the benefits may not outweigh the risks or side effects.* *Risk can be estimated using a range of standardised tools and clinical expertise.*	No effect on how many women are alive 5 and 10 years after diagnosis. Lower rate of recurrence of DCIS and lower rate of invasive breast cancer, compared with women who did not receive endocrine therapy or radiotherapy after surgery.
Side effects	All endocrine therapies: menopausal symptoms such as hot flushes. For tamoxifen: increased risk of thrombosis, endometrial cancer and possibly bone density loss in premenopausal women. For aromatase inhibitors: joint and muscle pain, urogenital symptoms and bone density loss.
Fertility and family planning	Effects on fertility and family planning as women should not become pregnant while taking tamoxifen, or within 2 months of stopping, because it may have adverse effects on the baby.

To find out why the committee made the 2018 recommendations on endocrine therapy for DCIS and how they might affect practice, see rationale and impact.

1.8 Adjuvant chemotherapy for invasive breast cancer

1.8.1 For people with breast cancer of sufficient risk that chemotherapy is indicated, offer a regimen that contains both a taxane[6] and an anthracycline[7]. **[2018]**

1.8.2 Discuss with people the benefits and risks of adding a taxane[6] to

anthracycline[7]-containing regimens. Topics to discuss include those in table 4 and:

- the benefits of reduced cardiac toxicity and reduced nausea
- the risks of additional side effects, including neuropathy, neutropenia and hypersensitivity
- the different side effects and dosing frequencies of different docetaxel and paclitaxel regimens, and the additional clinic visits that may be needed
- that absolute benefit is proportional to absolute risk of recurrence. **[2018]**

Table 4 Benefits and risks of adding a taxane to anthracycline-containing regimens and comparison of different taxane regimens

	Effect of adding a taxane to an anthracycline containing regimen	
	3-weekly docetaxel	Weekly or fortnightly paclitaxel
Effect on survival *NOTE: The benefit for an individual person will depend on the risk of their cancer returning. For people with low risk of recurrence, the benefits may not outweigh the risks or side effects.* *Risk can be estimated using a range of standardised tools and clinical expertise.*	Some evidence for improved outcomes including reducing the risk of breast cancer returning and increasing the chance of surviving.	
Benefits	Smaller doses of anthracyclines can be used, which can reduce the risk of side effects such as nausea and vomiting. Smaller cumulative doses of individual drugs may reduce long-term side effects, for example, cardiac toxicity and risk of second malignancies.	

Side effects	Additional side effects may include joint and muscle pain, nerve damage, higher rates of febrile neutropenia and hypersensitivity reactions. Some people have long-term hair loss (alopecia) after treatment with taxanes.	Additional side effects may include nerve damage and hypersensitivity reactions but febrile neutropenia is less likely than with 3-weekly docetaxel. Some people have long-term hair loss (alopecia) after treatment with taxanes. Weekly paclitaxel is tolerated best, but even fortnightly is better tolerated than 3-weekly docetaxel.
Administration	Visits to hospital every 3 weeks.	Visits to hospital every week or every 2 weeks.
Length of course	9 to 12 weeks (3 to 4 cycles).	9 to 12 weeks (9 to 12 doses)

1.8.3 Weekly and fortnightly paclitaxel should be available locally because these regimens are tolerated better than 3-weekly docetaxel, particularly in people with comorbidities. **[2018]**

> To find out why the committee made the 2018 recommendations on adjuvant chemotherapy for invasive breast cancer and how they might affect practice, see rationale and impact.

Biological therapy

1.8.4 Offer adjuvant trastuzumab for people with T1c and above HER2-positive invasive breast cancer, given at 3-week intervals for 1 year in combination with surgery, chemotherapy and radiotherapy as appropriate. **[2009, amended 2018]**

1.8.5 Consider adjuvant trastuzumab for people with T1a/T1b HER2-positive invasive breast cancer, taking into account any comorbidities, prognostic features and possible toxicity of chemotherapy. **[2018]**

To find out why the committee made the 2018 recommendation on biological therapy and how it might affect practice, see rationale and impact.

1.8.6 Assess cardiac function before starting treatment with trastuzumab. **[2009]**

1.8.7 Use trastuzumab with caution in people with HER2-positive invasive breast cancer who have any of the following:

- a baseline left ventricular ejection fraction (LVEF) of 55% or less
- a history of, or current, congestive heart failure
- a history of myocardial infarction
- angina pectoris needing medication
- cardiomyopathy
- cardiac arrhythmias needing medical treatment
- clinically significant valvular heart disease
- haemodynamic effective pericardial effusion
- poorly controlled hypertension. **[2009, amended 2018]**

1.8.8 Repeat cardiac function assessments every 3 months during trastuzumab treatment. If the LVEF drops by 10 percentage (ejection) points or more from baseline and to below 50%, suspend trastuzumab treatment. Restart trastuzumab only after reassessing cardiac function and discussing the possible benefits and risks. Cardiac function assessments should also be repeated every 6 months following discontinuation of treatment until 24 months from the last administration of trastuzumab. **[2009, amended 2018]**

1.9 Bisphosphonate therapy

Adjuvant bisphosphonate therapy

1.9.1 Offer bisphosphonates (zoledronic acid or sodium clodronate)[8] as adjuvant therapy to postmenopausal women with node-positive invasive breast cancer. **[2018]**

1.9.2 Consider bisphosphonates (zoledronic acid or sodium clodronate)[8] as adjuvant therapy for postmenopausal women with node-negative invasive breast cancer and a high risk[1] of recurrence. **[2018]**

1.9.3 Discuss the benefits and risks of bisphosphonate treatment with women, particularly the risk of osteonecrosis of the jaw, atypical femoral fractures and osteonecrosis of the external auditory canal. Follow the Medicines and Healthcare products Regulatory Agency/Commission on Human Medicines (MHRA/CHM) advice on bisphosphonates. **[2018]**

> To find out why the committee made the 2018 recommendations on adjuvant bisphosphonate therapy and how they might affect practice, see rationale and impact.

Bone health

1.9.4 Offer a baseline dual-energy X-ray absorptiometry (DEXA) scan to assess bone mineral density (BMD) in women with invasive breast cancer who are not receiving bisphosphonates as adjuvant therapy and who:

- are starting adjuvant aromatase inhibitor treatment **or**
- have treatment-induced menopause **or**
- are starting ovarian ablation/suppression therapy. **[2009, amended 2018]**

1.9.5 Do not offer a DEXA scan to women with invasive breast cancer who are receiving tamoxifen alone, regardless of their pretreatment menopausal status. **[2009]**

1.9.6 Offer bisphosphonates to women identified by algorithms 1 and 2 in Guidance for the management of breast cancer treatment-induced bone loss: a consensus position statement from a UK expert group (2008)[6]. **[2009]**

1.10 Radiotherapy

1.10.1 Use a radiotherapy technique that minimises the dose to the lung and heart. **[2018]**

1.10.2 Use a deep inspiratory breath-hold radiotherapy technique for people with

left-sided breast cancer to reduce the dose to the heart. **[2018]**

> To find out why the committee made the 2018 recommendations on radiotherapy techniques and how they might affect practice, see rationale and impact.

Radiotherapy after breast-conserving surgery

1.10.3 Offer whole-breast radiotherapy to women with invasive breast cancer who have had breast-conserving surgery with clear margins. **[2018]**

1.10.4 Consider partial breast radiotherapy (as an alternative to whole-breast radiotherapy) for women who have had breast-conserving surgery for invasive cancer (excluding lobular type) with clear margins and who:

- have a low absolute risk of local recurrence (defined as women aged 50 and over with tumours that are 3 cm or less, N0, ER-positive, HER2-negative and grade 1 to 2) **and**
- have been advised to have adjuvant endocrine therapy for a minimum of 5 years. **[2018]**

1.10.5 When considering partial breast radiotherapy (see recommendation 1.10.4), discuss the benefits and risks, and explain that:

- local recurrence with partial breast radiotherapy at 5 years is equivalent to that with whole-breast radiotherapy
- the risk of local recurrence beyond 5 years is not yet known
- there is a potential reduction in late adverse effects. **[2018]**

1.10.6 When delivering partial breast radiotherapy, use external beam radiotherapy. **[2018]**

1.10.7 Consider omitting radiotherapy for women who:

- have had breast-conserving surgery for invasive breast cancer with clear margins **and**
- have a very low absolute risk of local recurrence (defined as women aged 65 and over with tumours that are T1N0, ER-positive, HER2-negative and grade 1 to 2) **and**

- are willing to take adjuvant endocrine therapy for a minimum of 5 years. **[2018]**

1.10.8 When considering omitting radiotherapy for the population in recommendation 1.10.7, discuss the benefits and risks, including those in table 5, and explain that:

- without radiotherapy, local recurrence occurs in about 50 women per 1,000 at 5 years, and with radiotherapy, occurs in about 10 women per 1,000 at 5 years
- overall survival at 10 years is the same with or without radiotherapy
- there is no increase in serious late effects if radiotherapy is given (for example, congestive cardiac failure, myocardial infarction or secondary cancer). **[2018]**

Table 5 Benefits and risks of radiotherapy compared with no radiotherapy in the group of women at low risk described in recommendation 1.10.7

	Radiotherapy	No radiotherapy
Effect on local recurrence	On average, in 1,000 women, over 5 years local recurrence occurs in about 10 women, and does not occur in about 990 women.	On average, in 1,000 women, over 5 years local recurrence occurs in about 50 women, and does not occur in about 950 women.
Effect on survival	No difference in overall survival at 10 years.	No difference in overall survival at 10 years.
Risks	Possibility of short- and long-term adverse effects on the breast, and resulting cosmetic changes (such as skin soreness, changes to colour of skin, radiation fibrosis or stiffening of the breast tissue).	No short- or long-term adverse effects on the breast, or cosmetic changes.
Side effects	In this group of women at low risk, there is no increase in serious late side effects of radiotherapy (such as congestive cardiac failure, myocardial infarction or secondary cancer).	No side effects of radiotherapy will occur.
Administration	Given at the treatment centre 5 days a week for 3 weeks after surgery.	No need to attend the treatment centre for radiotherapy sessions.

1.10.9 Consider adjuvant radiotherapy for women with DCIS following breast-conserving surgery with clear margins, and discuss with them the possible benefits and risks of radiotherapy (also see surgery to the breast). **[2009, amended 2018]**

> To find out why the committee made the 2018 recommendations on radiotherapy after breast-conserving surgery and how they might affect practice, see rationale and impact.

Radiotherapy after mastectomy

1.10.10 Offer adjuvant postmastectomy radiotherapy to people with node-positive (macrometastases) invasive breast cancer or involved resection margins. **[2018]**

1.10.11 Consider adjuvant postmastectomy radiotherapy for people with node-negative T3 or T4 invasive breast cancer. **[2018]**

1.10.12 Do not offer radiotherapy following mastectomy to people with invasive breast cancer who are at low risk[1] of local recurrence (for example, most people who have lymph node-negative breast cancer). **[2018]**

> To find out why the committee made the 2018 recommendations on radiotherapy after mastectomy and how they might affect practice, see rationale and impact.

Dose fractionation

1.10.13 Use external beam radiotherapy giving 40 Gy in 15 fractions as standard practice for women with invasive breast cancer after breast-conserving surgery or mastectomy. **[2009]**

Breast boost following breast-conserving surgery

1.10.14 Offer an external beam boost to the tumour bed for women with invasive breast cancer and a high risk[1] of local recurrence, following whole-breast radiotherapy. **[2009, amended 2018]**

1.10.15 Inform women of the risk of side effects associated with an external beam boost to the tumour bed following whole-breast radiotherapy. **[2009, amended 2018]**

Radiotherapy to nodal areas

1.10.16 Do not offer adjuvant radiotherapy to regional lymph nodes to people with invasive breast cancer who have been shown to have histologically lymph node-negative breast cancer. **[2009, amended 2018]**

1.10.17 Do not offer adjuvant radiotherapy to the axilla after axillary clearance for invasive breast cancer. **[2009, amended 2018]**

1.10.18 Offer adjuvant radiotherapy to the supraclavicular fossa to people with invasive breast cancer and 4 or more involved axillary lymph nodes. **[2009]**

1.10.19 Offer adjuvant radiotherapy to the supraclavicular fossa to people with invasive breast cancer and 1 to 3 positive lymph nodes if they have other poor prognostic factors (for example, T3 and/or histological grade 3 tumours) and good performance status. **[2009]**

1.10.20 Consider including the internal mammary chain within the nodal radiotherapy target for people with node-positive (macrometastases) invasive breast cancer. **[2018]**

> To find out why the committee made the 2018 recommendation on radiotherapy to nodal areas and how it might affect practice, see rationale and impact.

Intraoperative radiotherapy

1.10.21 For guidance on intraoperative radiotherapy, see the NICE technology appraisal guidance on the intrabeam radiotherapy system for adjuvant treatment of early breast cancer. **[2018]**

1.11 Primary systemic therapy

Neoadjuvant chemotherapy

1.11.1 Offer neoadjuvant chemotherapy to people with ER-negative invasive breast cancer as an option to reduce tumour size. **[2018]**

1.11.2 Offer neoadjuvant chemotherapy to people with HER2-positive invasive breast cancer in line with the NICE technology appraisal on pertuzumab for the

neoadjuvant treatment of HER2-positive breast cancer. [2018]

1.11.3 Consider neoadjuvant chemotherapy for people with ER-positive invasive breast cancer as an option to reduce tumour size if chemotherapy is indicated. [2018]

> To find out why the committee made the 2018 recommendations on neoadjuvant chemotherapy and how they might affect practice, see rationale and impact.

Neoadjuvant chemotherapy regimens

1.11.4 For people with triple-negative invasive breast cancer, consider a neoadjuvant chemotherapy regimen that contains both a platinum[10] and an anthracycline. [2018]

1.11.5 Discuss the benefits and risks of adding a platinum[12] to an anthracycline-containing neoadjuvant chemotherapy regimen. Topics to discuss include those in table 6, and particularly the risk of increased toxicity. [2018]

Table 6 Benefits and risks of adding a platinum to anthracycline-containing neoadjuvant chemotherapy for triple-negative invasive breast cancer

	Effect of adding a platinum to anthracycline-containing (with or without taxane) neoadjuvant chemotherapy
Effect on breast conservation rate	Adding a platinum improves response rates compared with anthracycline-based (with or without taxane) chemotherapy. This may mean that some women who would otherwise need a mastectomy can be offered breast-conserving surgery.
Effect on pathological complete response rate (no residual cancer found at surgery)	Adding a platinum improves the chances of all signs of cancer disappearing in both the breast and lymph nodes in the armpit, compared with anthracycline-based (with or without taxane) neoadjuvant chemotherapy.
Effect on survival	No increase in overall survival with platinum-based chemotherapy.

Side effects *NOTE: Platinum-based therapy is only suitable for fit patients with no significant comorbidities.*	Adding a platinum may mean that side effects are more severe. Anaemia, thrombocytopenia, neutropenia and febrile neutropenia are seen more frequently with platinum-based chemotherapy. On average, if 1,000 women with triple-negative breast cancer receive platinum-containing neoadjuvant chemotherapy, about 70 additional women would experience severe or life-threatening side effects compared with non-platinum neoadjuvant chemotherapy. Bone marrow suppression and renal problems are likely in older people.
Licensed status	At the time of publication (July 2018), platinums did not have UK marketing authorisation for this indication.

To find out why the committee made the 2018 recommendations on neoadjuvant chemotherapy regimens and how they might affect practice, see rationale and impact.

Neoadjuvant endocrine therapy

1.11.6 Consider neoadjuvant endocrine therapy for postmenopausal women with ER-positive invasive breast cancer as an option to reduce tumour size if there is no definite indication for chemotherapy. **[2018]**

1.11.7 Advise premenopausal women that neoadjuvant chemotherapy may be more likely to produce a clinical response than neoadjuvant endocrine therapy, but that some tumours do respond to neoadjuvant endocrine therapy. **[2018]**

1.11.8 Discuss with women the benefits and risks of neoadjuvant endocrine therapy compared with neoadjuvant chemotherapy. Topics to discuss include those in table 7. **[2018]**

Table 7 Benefits and risks of neoadjuvant endocrine therapy compared with neoadjuvant chemotherapy

	Neoadjuvant endocrine therapy	Neoadjuvant chemotherapy

Definition	Tamoxifen or an aromatase inhibitor started before surgery. Only an option for women with ER-positive breast cancer.	Chemotherapy given before surgery. Only an option for people who would be recommended adjuvant (after surgery) chemotherapy.
Administration	Tablet taken once a day at home.	Intravenous administration in hospital, as an outpatient.
Effectiveness	**For postmenopausal women:** may be as effective as neoadjuvant chemotherapy in terms of breast conservation rates and shrinking the tumour. **For premenopausal women:** less effective than neoadjuvant chemotherapy at shrinking the tumour (but some tumours may respond so may be effective in some women).	**For postmenopausal women:** effective at improving breast conservation rates and shrinking the tumour. **For premenopausal women:** more effective than endocrine therapy at shrinking the tumour.
Potential disadvantages	If neoadjuvant endocrine therapy is not effective, then women may proceed to surgery earlier or may still need to have chemotherapy, either before or after surgery.	

Side effects	All endocrine therapies: menopausal symptoms such as hot flushes. For tamoxifen: increased risk of thrombosis and endometrial cancer. For aromatase inhibitors: joint and muscle pain, urogenital symptoms, bone density loss (may also occur with tamoxifen in premenopausal women). Side effects are usually reversible. May allow women to avoid the additional side effects of chemotherapy (although women may still need adjuvant chemotherapy after surgery).	Side effects may include nausea and vomiting, risk of infections that may be life threatening, fatigue, neuropathy, cardiac toxicity, diarrhoea, constipation, sore mouth, skin and nail changes, risk of blood clots, risk of second malignancies, fluid retention, allergic reactions and hair loss. Side effects may persist long term.
Fertility and family planning	Women should not become pregnant while taking tamoxifen, or within 2 months of stopping, because it may have adverse effects on the baby.	Often causes temporary infertility. May cause permanent infertility.
Length of course	May take longer than chemotherapy to shrink the tumour enough for breast-conserving surgery.	The duration of neoadjuvant chemotherapy is shorter than neoadjuvant endocrine therapy.

To find out why the committee made the 2018 recommendations on neoadjuvant endocrine therapy and how they might affect practice, see rationale and impact.

Radiotherapy after neoadjuvant chemotherapy

1.11.9 Offer local treatment with mastectomy (or, in exceptional cases, breast-conserving surgery) followed by radiotherapy to people with locally advanced or inflammatory breast cancer that has been treated with neoadjuvant chemotherapy. **[2009]**

1.11.10 Offer postmastectomy radiotherapy after neoadjuvant chemotherapy if post-treatment histology shows node-positive (macrometastases) breast cancer or involved resection margins. **[2018]**

1.11.11 Offer postmastectomy radiotherapy after neoadjuvant chemotherapy if pretreatment investigations show node-positive (macrometastases) breast cancer. **[2018]**

1.11.12 Consider postmastectomy radiotherapy after neoadjuvant chemotherapy if post-treatment histology shows node-negative T3 breast cancer. **[2018]**

1.11.13 Consider postmastectomy radiotherapy after neoadjuvant chemotherapy if pretreatment investigations show node-negative T3 breast cancer. **[2018]**

> To find out why the committee made the 2018 recommendations on radiotherapy after neoadjuvant chemotherapy and how they might affect practice, see rationale and impact.

1.12 Complications of local treatment and menopausal symptoms

Lymphoedema

1.12.1 Inform people with breast cancer about the risk of developing lymphoedema, and give them relevant written information before treatment with surgery and radiotherapy. **[2009]**

1.12.2 Give advice on how to prevent infection that may cause or exacerbate lymphoedema to people who have had treatment for breast cancer. **[2009, amended 2018]**

1.12.3 When informing people with breast cancer about the risk of developing

lymphoedema, advise them that:

- they do not need to restrict their physical activity
- there is no consistent evidence of increased risk of lymphoedema associated with air travel, travel to hot countries, manicures, hot-tub use or sports injuries
- there is no consistent evidence of increased risk of lymphoedema associated with medical procedures (for example, blood tests, injections, intravenous medicines and blood pressure measurement) on the treated side, and the decision to perform medical procedures using the arm on the treated side should depend on clinical need and the possibility of alternatives. [2018]

1.12.4 Ensure that people with breast cancer who develop lymphoedema have rapid access to a specialist lymphoedema service. [2009]

> To find out why the committee made the 2018 recommendation on lymphoedema and how it might affect practice, see rationale and impact.

Arm mobility

1.12.5 All breast units should have written local guidelines agreed with the physiotherapy department for postoperative physiotherapy. [2009]

1.12.6 Identify pre-existing shoulder conditions preoperatively in people with breast cancer, as this may inform further decisions on treatment. [2009]

1.12.7 Give instructions on functional exercises, which should start the day after surgery, to people with breast cancer. This should include relevant written information from a member of the breast or physiotherapy team. [2009]

1.12.8 Refer people to the physiotherapy department if they report a persistent reduction in arm and shoulder mobility after breast cancer treatment. [2009]

Menopausal symptoms

1.12.9 Stop systemic hormone replacement therapy (HRT) in women who are diagnosed with breast cancer. [2009]

1.12.10 Do not offer HRT (including oestrogen/progestogen combination) routinely to women with menopausal symptoms and a history of breast cancer. In exceptional circumstances, offer HRT[11] to women with severe menopausal symptoms and with whom the associated risks have been discussed. **[2009]**

1.12.11 Offer women information and counselling about the possibility of early menopause and menopausal symptoms associated with breast cancer treatment. **[2009]**

1.12.12 Consider selective serotonin reuptake inhibitor (SSRI) antidepressants[12] for women with breast cancer for relieving menopausal symptoms, particularly hot flushes, but not for those taking tamoxifen. **[2009, amended 2018]**

1.12.13 Do not offer soy (isoflavone), red clover, black cohosh, vitamin E or magnetic devices to treat menopausal symptoms in women with breast cancer. **[2009]**

1.13 Follow-up

Follow-up imaging

1.13.1 Offer annual mammography to all people with breast cancer, including DCIS, until they enter the NHS Breast Screening Programme (NHSBSP) in England or the Breast Test Wales Screening Programme (BTWSP) in Wales. People diagnosed with breast cancer who are already eligible for screening should have annual mammography for 5 years. **[2009]**

1.13.2 Do not offer mammography of the ipsilateral soft tissues after mastectomy. **[2009]**

1.13.3 Do not offer ultrasound or MRI for routine post-treatment surveillance in people who have had treatment for invasive breast cancer or DCIS. **[2009]**

Clinical follow-up

1.13.4 People who have had treatment for breast cancer should have an agreed, written care plan, which should be recorded by a named healthcare professional (or professionals). A copy should be sent to the GP and a copy given to the person. This plan should include:

- designated named healthcare professionals
- dates for review of any adjuvant therapy
- details of surveillance mammography
- signs and symptoms to look for and seek advice on
- contact details for immediate referral to specialist care **and**
- contact details for support services, for example, support for people with lymphoedema. **[2009]**

1.14 Lifestyle

1.14.1 Advise people with breast cancer that a healthy lifestyle is associated with a lower risk of recurrence, and that this should include:

- achieving and maintaining a healthy weight (see the NICE guidelines on preventing excess weight gain and obesity)
- limiting alcohol intake to below 5 units per week **and**
- regular physical activity (see the NICE guideline on physical activity for adults). **[2018]**

1.14.2 For guidance on smoking cessation, see the NICE guideline on stop smoking interventions and services. **[2018]**

> To find out why the committee made the 2018 recommendations on lifestyle and how they might affect practice, see rationale and impact.

[1] Risk can be estimated using a range of standardised tools and clinical expertise.

[2] The potential limitations in versions of PREDICT after 2.0 may differ from those listed here.

[3] Please refer to the summary of product characteristics for individual aromatase inhibitors because there are differences in their licensed indications.

[4] Please refer to the summary of product characteristics for individual aromatase inhibitors because there are differences in their licensed indications. At the time of publication (July 2018),

aromatase inhibitors did not have a UK marketing authorisation for treatment beyond 5 years.

[5] Medium or high risk may include people who have lymph node-positive breast cancer, with tumours that are T2 or greater and higher grade. Low risk may include people with lymph node-negative breast cancer, with smaller or lower-grade tumours.

[6] Please refer to the summary of product characteristics for individual taxanes because there are differences in their licensed indications.

[7] Please refer to the summary of product characteristics for individual anthracyclines because there are differences in their licensed indications.

[8] Although this use is common in UK clinical practice, at the time of publication (July 2018), bisphosphonates did not have UK marketing authorisations for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's Prescribing guidance: prescribing unlicensed medicines for further information.

[9] This guidance is not NICE accredited.

[10] Although this use is common in UK clinical practice, at the time of publication (July 2018), platinums did not have UK marketing authorisations for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's Prescribing guidance: prescribing unlicensed medicines for further information.

[11] At the time of publication (July 2018), HRT did not have a UK marketing authorisation for this indication and is contraindicated in women with a history of breast cancer. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's Prescribing guidance: prescribing unlicensed medicines for further information.

[12] At the time of publication (July 2018), SSRIs did not have a UK marketing authorisation for this indication. The prescriber should follow relevant professional guidance, taking full responsibility for the decision. Informed consent should be obtained and documented. See the General Medical Council's Prescribing guidance: prescribing unlicensed medicines for further information.

Recommendations for research

The guideline committee has made the following recommendations for research.

Key recommendations for research

1 Surgery to the breast

What is the optimum tumour-free margin width after breast-conserving surgery for women with ductal carcinoma in situ (DCIS) and invasive breast cancer?

To find out why the committee made the research recommendation on surgery to the breast, see rationale and impact.

2 Adjuvant bisphosphonate therapy

Which groups of people with early and locally advanced breast cancer would benefit from the use of adjuvant bisphosphonates?

To find out why the committee made the research recommendation on bisphosphonates, see rationale and impact.

3 Breast reconstruction

What are the long-term outcomes for breast reconstruction in women having radiotherapy to the chest wall?

To find out why the committee made the research recommendation on postmastectomy radiotherapy, see rationale and impact.

4 Neoadjuvant endocrine therapy in premenopausal women

Is neoadjuvant endocrine therapy safe in premenopausal women with early breast cancer?

To find out why the committee made the research recommendation on neoadjuvant endocrine therapy in premenopausal women, see rationale and impact.

5 Neoadjuvant endocrine therapy in postmenopausal women

Is there a benefit for neoadjuvant endocrine therapy in postmenopausal women with early breast cancer?

To find out why the committee made the research recommendation on neoadjuvant endocrine therapy in postmenopausal women, see rationale and impact.

6 Neoadjuvant treatment

What are the indications for postmastectomy radiotherapy after neoadjuvant chemotherapy?

To find out why the committee made the research recommendation on neoadjuvant treatment, see rationale and impact.

Rationale and impact

These sections briefly explain why the committee made the recommendations and how they might affect practice. They link to details of the evidence and a full description of the committee's discussion.

Providing information and psychological support

Recommendation 1.2.4

Why the committee made the recommendation

The committee agreed, based on their clinical expertise, that continued improvement in breast cancer survival as well as post-diagnosis quality of life needs ongoing research into new or refined treatment options to allow further optimisation of care.

How the recommendation might affect practice

Recruitment into clinical trials wherever possible is already standard practice so the recommendation is unlikely to result in a change in practice.

Return to recommendations

Recommendation 1.2.5

Why the committee made the recommendation

The committee agreed, based on their clinical expertise, that people having treatment for breast cancer should be advised about options for preserving their fertility, so cross-referred to the existing NICE guideline on this topic.

How the recommendation might affect practice

Discussion of fertility options is already standard practice so the recommendation is unlikely to result in a change in practice.

Return to recommendations

Surgery to the breast

Recommendations 1.3.1 and 1.3.2

Why the committee made the recommendations

There was some evidence that there was a reduced risk of ductal carcinoma in situ (DCIS) local recurrence if tissue margins were greater than 0 mm, so the committee recommended further surgery (re-excision or mastectomy) to extend the margins if needed. Although there was no consistent evidence about tissue margins for invasive breast cancer, the committee agreed that further surgery should be offered.

The committee agreed that complete excision of the tumour with clear margins was essential for the high-quality care of people with DCIS or invasive breast cancer.

Although there was evidence that aiming for wider margins reduced local recurrence, this did not improve overall survival. In addition, aiming for wider margins could lead to some people having unnecessary extra surgery. Given this uncertainty, the committee agreed the importance of personalised care and discussion to decide whether further surgery is needed.

There was not enough evidence to clearly define an optimum margin width between 0 mm and 2 mm to minimise local recurrence rates and minimise further surgery, so the committee agreed that this was an important topic for further research.

How the recommendations might affect practice

The rates of further surgery currently vary across the country. Although the committee noted that the recommendations will reinforce current best practice, there may be some centres that will need to amend their practice in order to follow these recommendations.

Full details of the evidence and the committee's discussion are in evidence review A: surgery to the breast.

Return to recommendations

Evaluation and management of a positive axillary lymph node

Recommendations 1.4.7 to 1.4.10

Why the committee made the recommendations

There was no new evidence that led the committee to change from the existing recommended practice (as recommended in the previous NICE guideline CG80) of:

- offering axillary clearance to people with preoperatively pathologically proven involvement of the axillary lymph nodes
- not offering axillary treatment after primary surgery to people with isolated tumour cells in their sentinel lymph nodes.

The committee agreed that current evidence shows that further axillary treatment after primary surgery does not improve survival for people with micrometastases and there are risks such as lymphoedema, therefore further treatment should not be offered to this population. There were unclear benefits and risks of further axillary treatment after primary surgery in people with only 1 or 2 sentinel lymph node macrometastases who have had breast-conserving surgery and have been advised to have whole-breast radiotherapy and systemic therapy, so the committee agreed that the risks and benefits of further treatment should be discussed with this group.

Studies of neoadjuvant therapy were excluded from the evidence review.

How the recommendations might affect practice

The committee agreed that the recommendations will result in a minor change in practice because some centres currently use mainly surgery and may not use radiotherapy. In addition, more time may need to be factored in to plan and deliver radiotherapy treatment.

Full details of the evidence and the committee's discussion are in evidence review B: management of the positive axilla.

Return to recommendations

Breast reconstruction

Recommendations 1.5.1 to 1.5.4

Why the committee made the recommendations

There was not much good evidence, but the committee agreed that the main benefits of immediate breast reconstruction compared with delayed reconstruction are improved aesthetic satisfaction, improved symmetry, improved health-related quality of life, lower overall rates of complications and a reduced need for further surgery. The committee agreed that in some circumstances, there are advantages to delayed reconstruction compared with immediate reconstruction (for example, reduced mastectomy flap loss, and capsular contracture). Therefore, delayed reconstruction should also be an option for women who wish to have a reconstruction after mastectomy. The committee also agreed that the option of no reconstruction should also be discussed, because this may be the preferred option for some women.

In addition, although radiotherapy can impact on outcomes after breast reconstruction, there was no consistent evidence for worse outcomes between radiotherapy delivered after immediate reconstructions compared with radiotherapy before delayed reconstructions. Therefore, the committee agreed that immediate reconstruction should be offered regardless of plans for chest wall radiotherapy.

There is little evidence regarding longer-term outcomes and different types of reconstruction. Because of this, the committee agreed that more research is needed to understand whether immediate breast reconstruction or delayed breast reconstruction is better in women who may need postmastectomy radiotherapy.

How the recommendations might affect practice

The recommendations may result in a substantial change in practice because many centres do not routinely offer immediate breast reconstruction to all women (especially those who have been advised to have radiotherapy). The impact will depend on how many immediate reconstructions are already carried out. In addition, the uptake of immediate breast reconstruction will also depend on women's preferences. There may be cost savings associated with immediate reconstructions because fewer surgical procedures are needed (reconstruction is done at the same time as mastectomy and there are lower rates of additional symmetrisation surgery).

Full details of the evidence and the committee's discussion are in evidence review I: postmastectomy radiotherapy.

Return to recommendations

Predictive factors

Recommendations 1.6.1, 1.6.3 and 1.6.5

Why the committee made the recommendations

There was not enough good evidence, so the committee agreed, using a formal consensus scoring system and their knowledge and experience, that progesterone receptor (PR) status should be assessed for all invasive breast cancers because:

- it will help when tailoring adjuvant therapy
- it will reduce delays in starting treatment
- if people are already having testing at this stage, their PR status can be assessed without them having to wait for additional test results.

The committee also agreed that oestrogen receptor (ER), PR and human epidermal growth receptor 2 (HER2) status assessments should be requested simultaneously at the time of initial diagnosis to ensure that results are available at the initial preoperative multidisciplinary team meeting (as well as the postoperative meeting). This will avoid delays and the need for additional discussions.

How the recommendations might affect practice

Most people with invasive breast cancer have PR testing in current practice, although it is not always performed at diagnosis. The recommendations should reduce variation in practice and delays in starting treatment, and the need for pathology results to be discussed at more than 1 multidisciplinary meeting, and so may lead to a small cost-saving.

Full details of the evidence and the committee's discussion are in evidence review C: adjuvant systemic therapy planning.

Return to recommendations

Adjuvant therapy planning

Recommendations 1.6.8 and 1.6.9

Why the committee made the recommendations

Good evidence showed that the prognostic tool PREDICT is an accurate tool to estimate prognosis and the benefits of treatment in most people.

How the recommendations might affect practice

The committee agreed that most healthcare professionals already use the PREDICT tool, so this recommendation will not mean a big change in practice.

Full details of the evidence and the committee's discussion are in evidence review C: adjuvant systemic therapy planning.

Return to recommendations

Ovarian function suppression

Recommendations 1.7.4 and 1.7.5

Why the committee made the recommendations

There was evidence that ovarian function suppression increased overall survival when combined with tamoxifen, and that women who have had chemotherapy benefited more. However, ovarian function suppression did not improve disease-free survival. In addition, it induces a temporary menopause and can worsen the menopausal symptoms seen with tamoxifen.

Given the limited evidence of benefits and the side effects of the treatment, the committee agreed that healthcare professionals should discuss the potential benefits and risks with women. This will help women to decide which treatment is right for them.

How the recommendations might affect practice

There is variation among centres in the use of ovarian function suppression, so the recommendations should lead to greater consistency and improve access to the treatment, even though not all women will wish to have it. There will be an increase in required resources for centres that do not currently provide ovarian function suppression, because additional

appointments will be needed to administer the medication and monitor side effects. However, this was not anticipated to be a substantial cost increase because of the number of centres already offering ovarian function suppression. Further, increased costs will be at least partially offset by improvements in survival outcomes.

Full details of the evidence and the committee's discussion are in evidence review D: endocrine therapy for invasive disease.

Return to recommendations

Extended endocrine therapy

Recommendations 1.7.6 to 1.7.9

Why the committee made the recommendations

Good evidence showed that switching to an aromatase inhibitor after 5 years of tamoxifen improved disease-free survival compared with postmenopausal women who had only received tamoxifen for 5 years, with the benefits being greater in those women who had a greater risk of disease recurrence.

The evidence showed no benefit in terms of disease-free survival or overall survival from continuing tamoxifen beyond 5 years. However, some of the studies on tamoxifen were conducted in the 1980s and may not be relevant to current practice. In the committee's experience, continuing tamoxifen can be beneficial for some women.

However, evidence showed that being on endocrine therapy for more than 5 years can increase the risk of problems such as endometrial cancer, osteoporosis, toxicity and phlebitis. The committee agreed that people will often prioritise survival even if this means they will have a reduced quality of life, but that people need to be informed about the possible benefits and risks so they can make a choice.

Because of the risk of problems with taking endocrine therapy for more than 5 years, the committee agreed that healthcare professionals should discuss the potential benefits and risks with women to help them make an informed choice about treatment, based on their own risk factors.

How the recommendations might affect practice

Some centres already review treatment at 5 years, and continue endocrine therapy with tamoxifen or an aromatase inhibitor when it could benefit women. Because a large number of women will be affected by these recommendations, the resource impact will be large for centres that are not currently providing treatment after 5 years.

Full details of the evidence and the committee's discussion are in evidence review D: endocrine therapy for invasive disease.

Return to recommendations

Endocrine therapy for ductal carcinoma in situ

Recommendations 1.7.10 to 1.7.12

Why the committee made the recommendations

There was good evidence that tamoxifen after breast-conserving surgery for ER-positive DCIS improved disease-free survival and reduced rates of local recurrence in women who did not have radiotherapy. Because of their concerns about over-treatment, the committee agreed that women who were at higher risk (those who should have had radiotherapy, but who did not receive it) would benefit more. There was no evidence available for aromatase inhibitors; however, the committee agreed they would likely produce similar improvements in disease-free survival and reductions in local recurrence as tamoxifen. Therefore, the committee recommended endocrine therapy, rather than specifically tamoxifen.

The committee agreed that the benefits and risks of endocrine therapy should be discussed with the woman because of the potential treatment-related complications such as menopausal symptoms, and the impact on family planning.

How the recommendations might affect practice

Offering endocrine therapy after initial treatment of DCIS will be a change of practice because it is not currently routinely offered to these women. However, because of the small number of people with DCIS who will not receive radiotherapy, and the low cost of the medicines, the committee agreed that the impact will not be significant.

Full details of the evidence and the committee's discussion are in evidence review D: endocrine

therapy for invasive disease.

Return to recommendations

Adjuvant chemotherapy for invasive breast cancer

Recommendations 1.8.1 to 1.8.3

Why the committee made the recommendations

There was good evidence of improved survival when taxanes are added to anthracycline-based chemotherapy in people with node-positive and node-negative breast cancer. In both groups, the benefits and risks of treatment should be discussed because of the potential side effects associated with taxanes. Three-weekly docetaxel was identified as a regimen with potentially more toxicity than weekly or fortnightly paclitaxel.

How the recommendations might affect practice

These recommendations may result in a substantial change in practice because of increased taxane use, particularly for people with node-negative breast cancer and comorbidities.

In addition, there will be an increase in weekly and fortnightly chemotherapy regimens being offered (for people who cannot tolerate 3-weekly regimens). These regimens have a higher cost because they are more resource intensive, and may affect capacity in chemotherapy services.

Full details of the evidence and the committee's discussion are in evidence review E: adjuvant chemotherapy.

Return to recommendations

Biological therapy

Recommendation 1.8.5

Why the committee made the recommendation

There was evidence that adjuvant trastuzumab can improve disease-free survival and overall survival in some people with T1a and T1b HER2-positive invasive breast cancer who were treated with adjuvant trastuzumab and chemotherapy. However, only a small number of people will benefit

from this treatment and, because trastuzumab can cause heart problems, it is important to avoid offering it to people who do not need it. Because of this, the committee agreed that adjuvant trastuzumab should be an option for women with T1a and T1b tumours rather than a standard treatment.

Combined chemotherapy and trastuzumab was not found to be cost effective when compared to chemotherapy alone. However, the committee agreed that it was more appropriate to compare combined chemotherapy and trastuzumab with no treatment, because these are the strategies that are likely to be used in clinical practice. Because it is the HER2-positivity that increases risk of recurrence for people with small (T1a and T1b) tumours, it does not make sense from a clinical perspective to not treat the component that is increasing risk (that is, trastuzumab treatment for HER2-positivity). Further, the effect of chemotherapy alone in the economic model may be overestimated because the data may not fully reflect the population under consideration.

How the recommendation might affect practice

Currently, T1 tumours are not routinely treated with adjuvant trastuzumab, so this recommendation will lead to a change in practice. However, the committee agreed that the number of additional people having treatment would be small and so the impact on current practice would be minor and unlikely to require a substantial increase in resources.

Full details of the evidence and the committee's discussion are in evidence review F: adjuvant biological therapy.

Return to recommendations

Adjuvant bisphosphonate therapy

Recommendations 1.9.1 to 1.9.3

Why the committee made the recommendations

There was good evidence that treatment with sodium clodronate and zoledronic acid improved disease-free and overall survival in postmenopausal women with node-positive invasive breast cancer.

There was little evidence of benefit for other bisphosphonates. The committee recommended considering zoledronic acid or sodium clodronate treatment for other high-risk populations (such as postmenopausal women with node-negative invasive breast cancer and a high risk of

recurrence), based on the evidence that sodium clodronate has overall survival benefits in mixed populations.

Although there is evidence that intravenous (IV) bisphosphonates have a higher risk of osteonecrosis of the jaw, oral bisphosphonates have a higher risk of gastrointestinal problems. There is also a risk of atypical femoral fractures and osteonecrosis of the external auditory canal with bisphosphonates. Because each drug and regimen has different risks, the potential benefits and risks should be discussed with women to help them make an informed choice.

There was little evidence on survival, particularly for premenopausal women on ovarian suppression, those with node-positive or node-negative disease, and those with positive or negative oestrogen or progestogen statuses. There was not enough evidence to make a recommendation relating to the use of adjuvant bisphosphonates in premenopausal women. The committee agreed that further research is needed to determine the long-term survival benefits and the groups of people most likely to benefit from adjuvant bisphosphonates.

The committee did not look at the evidence relating to the use of bisphosphonates for bone health or for the use of baseline dual-energy X-ray absorptiometry (DEXA) scanning, so did not make any new recommendations.

How the recommendations might affect practice

Bisphosphonates are not consistently offered as adjuvant treatment, so this recommendation may lead to an increase in prescribing.

GPs may need to monitor people taking oral bisphosphonates, but this is likely to be an annual review so would not have a large workload impact. However, people may make more GP visits if they have side effects from bisphosphonate treatment.

The committee agreed that IV bisphosphonates would usually be administered at the same time as chemotherapy drugs for the first 6 months of treatment, so this would not result in extra hospital visits for this period. After that, extra visits for administration and monitoring may be needed.

Full details of the evidence and the committee's discussion are in evidence review G: adjuvant bisphosphonates.

Return to recommendations

Radiotherapy techniques

Recommendation 1.10.1

Why the committee made the recommendation

There was good evidence that radiotherapy to the internal mammary nodes reduced locoregional recurrence and improved survival. However, the committee took into account the potential for lung and heart toxicity, so recommended using a radiotherapy technique that minimises this risk.

How the recommendation might affect practice

This recommendation is likely to need a change in practice for many centres. There will be some impact on resources in order to implement this recommendation because additional training will be needed and local protocols will need developing. However, the long-term impact on resources will be minimal: some additional planning time will be needed but there is no impact on the length or number of radiotherapy sessions.

Full details of the evidence and the committee's discussion are in evidence review H: breast radiotherapy.

Return to recommendations

Recommendation 1.10.2

Why the committee made the recommendation

There was evidence that deep inspiratory breath-hold radiotherapy techniques reduce the mean radiotherapy heart dose for adults with left-sided invasive breast cancer receiving whole-breast radiotherapy. The committee did not identify any harms. There was also evidence that deep inspiration breath-hold radiotherapy techniques did not reduce the target coverage of whole-breast radiotherapy.

There was no evidence about the use of deep inspiration breath-hold radiotherapy techniques for people with right-sided breast cancer, so the committee did not make separate recommendations for this subgroup.

How the recommendation might affect practice

Currently, deep inspiratory breath-hold radiotherapy techniques are not routinely offered to

people with invasive breast cancer having whole-breast radiotherapy. However, the committee noted that the Royal College of Radiologists has produced consensus statements that advise using this technique, and that many centres already offer it.

The recommendation will ensure consistent practice and ensure that people can access the best care.

Full details of the evidence and the committee's discussion are in evidence review H: breast radiotherapy.

Return to recommendations

Radiotherapy after breast-conserving surgery

Recommendations 1.10.3, 1.10.7 and 1.10.8

Why the committee made the recommendations on whole-breast radiotherapy and omitting radiotherapy

There is evidence that whole-breast radiotherapy after breast-conserving surgery reduces the risk of recurrence and increases overall survival. It also decreases rates of depression and anxiety.

However, because the risk of breast cancer recurring at 5 years is very low and there are harms associated with radiotherapy, the benefits of radiotherapy for women with a very low risk of recurrence are less certain. For these women, the committee agreed that healthcare professionals should fully discuss the benefits and risks with women before a decision is made.

How the recommendations might affect practice

Most women are already offered radiotherapy after breast-conserving surgery so this reflects current practice, but more time may be needed to discuss the balance of benefits and risks with women.

Full details of the evidence and the committee's discussion are in evidence review H: breast radiotherapy.

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Recommendations 1.10.4 to 1.10.6

Why the committee made the recommendations on partial breast radiotherapy

Good evidence showed that partial breast radiotherapy led to similar results to whole-breast radiotherapy after breast-conserving surgery in women with a low risk of local recurrence. In addition, it may have fewer treatment-related adverse effects. There was evidence for multicatheter interstitial brachytherapy but this was not recommended because it is not currently available in England.

How the recommendations might affect practice

The committee was aware that current practice for external beam partial breast radiotherapy after breast-conserving surgery is based on the Royal College of Radiologists' 2016 consensus statement, so there would be no change to recommended practice.

Full details of the evidence and the committee's discussion are in evidence review H: breast radiotherapy.

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Radiotherapy after mastectomy

Recommendations 1.10.10to 1.10.12

Why the committee made the recommendations

The committee agreed that adjuvant postmastectomy radiotherapy should be offered to people who have macroscopically node-positive invasive breast cancer or have involved resection margins. This is because the evidence showed a beneficial effect on survival and local recurrence. Although the evidence was limited and the committee acknowledged that radiotherapy is associated with lung and cardiac morbidity, they concluded that for this group of women, the benefits of radiotherapy outweigh the harms.

There was evidence of a beneficial effect of postmastectomy radiotherapy on local recurrence and overall survival for people with node-negative invasive breast cancer. However, the committee agreed that there was a risk of over-treatment if all people with node-negative invasive breast cancer received postmastectomy radiotherapy. Therefore, the committee recommended that adjuvant postmastectomy radiotherapy should be considered for people with node-negative T3 or

T4 invasive breast cancer. There was no evidence for this specific subgroup but they would be considered at increased risk of recurrence and mortality relative to smaller, node-negative invasive breast cancers because of the size of the tumour.

The committee agreed that radiotherapy after mastectomy should not be offered to women with early invasive breast cancer who are at low risk of local recurrence (for example, most women who are lymph node-negative) because the evidence showed limited benefit in survival and local recurrence.

How the recommendations might affect practice

The committee agreed that the recommendations will reinforce current practice, so there would be little change in practice.

Full details of the evidence and the committee's discussion are in evidence review I: postmastectomy radiotherapy.

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Radiotherapy to nodal areas

Recommendation 1.10.20

Why the committee made the recommendation

There was good evidence that radiotherapy to the internal mammary nodes reduced locoregional recurrence and improved survival. However, the committee took into account the potential for lung and heart toxicity, and agreed the importance of using a radiotherapy technique that minimises this risk.

How the recommendation might affect practice

This recommendation is likely to need a change in practice for many centres. There will be some impact on resources in order to implement this recommendation because additional training will be needed and local protocols will need developing. However, the long-term impact on resources will be minimal: some additional planning time will be needed but there is no impact on the length or number of radiotherapy sessions.

Full details of the evidence and the committee's discussion are in evidence review H: breast

radiotherapy.

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Neoadjuvant chemotherapy

Recommendations 1.11.1 to 1.11.3

Why the committee made the recommendations

There was good evidence to say that having chemotherapy before surgery (neoadjuvant chemotherapy) enables some women to have breast-conserving surgery who would otherwise have had total removal of their breast. The committee agreed that the response to neoadjuvant therapy could help to guide the choice of subsequent adjuvant therapy.

How the recommendations might affect practice

The committee agreed that the recommendations would not result in a major change in practice because neoadjuvant chemotherapy is already offered in many centres. These recommendations will help improve consistency in practice.

Full details of the evidence and the committee's discussion are in evidence review J: neoadjuvant treatment of early and locally advanced breast cancer.

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Neoadjuvant chemotherapy regimens

Recommendations 1.11.4 and 1.11.5

Why the committee made the recommendations

There was evidence that platinum-containing neoadjuvant chemotherapy regimens can improve pathological complete response (pCR) rate and breast conservation rate in people with triple-negative invasive breast cancer. However, the committee took into account that platinum-containing regimens can cause anaemia, thrombocytopenia, neutropenia and febrile neutropenia, and bone marrow problems and renal problems in older people. The committee agreed that healthcare professionals should have a full discussion with people about the benefits and risks of these regimens.

There was no evidence on people with the BRCA germline mutation, so the committee did not make separate recommendations for this subgroup.

How the recommendations might affect practice

Currently, platinum-containing neoadjuvant chemotherapy is not routinely offered to people with triple-negative early and locally advanced breast cancer, although the committee was aware that some centres may offer it. The recommendations will therefore bring a change in practice and will make practice more consistent across the NHS. The committee estimated that approximately 30–40% of people receiving neoadjuvant chemotherapy may be affected by this recommendation.

Full details of the evidence and the committee's discussion are in evidence review J: neoadjuvant treatment of early and locally advanced breast cancer.

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Neoadjuvant endocrine therapy

Recommendations 1.11.6 to 1.11.8

Why the committee made the recommendations

For postmenopausal women, there was some evidence that breast conservation rates, changes in tumour size and overall survival are the same with neoadjuvant endocrine therapy and neoadjuvant chemotherapy. Endocrine therapy is safer and has fewer side effects than chemotherapy, but there was not enough evidence to recommend endocrine therapy over chemotherapy for every woman. The committee agreed that healthcare professionals should discuss the potential benefits and risks with women, to help them decide which treatment is right for them and that more research is needed to say whether neoadjuvant endocrine therapy is as effective as neoadjuvant chemotherapy.

The evidence for premenopausal women showed that neoadjuvant chemotherapy was more effective than endocrine therapy, but that endocrine therapy may be effective in some women. However, some women may prefer endocrine therapy because it is safer and has fewer side effects. Because of this, the committee agreed that healthcare professionals should discuss the potential benefits and risks with women, to help them decide which treatment is right for them. The committee agreed that more research is needed on the long-term safety of neoadjuvant endocrine therapy, and to identify which premenopausal women will benefit from it.

How the recommendations might affect practice

Neoadjuvant endocrine therapy is already being used, although there may be an increase in the number of people being offered it.

Full details of the evidence and the committee's discussion are in evidence review J: neoadjuvant treatment of early and locally advanced breast cancer.

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Radiotherapy after neoadjuvant chemotherapy

Recommendations 1.11.10to 1.11.13

Why the committee made the recommendations

There was not enough evidence to recommend subgroups of women in whom postmastectomy radiotherapy could be safely omitted after neoadjuvant chemotherapy. Therefore, the committee agreed that the recommendations for postmastectomy radiotherapy among people who have not received neoadjuvant chemotherapy applied to this population.

People with node-negative T4 cancer were not included in this review because they are covered by the recommendation from the previous guideline which has been retained.

Women who respond well to neoadjuvant chemotherapy may derive less benefit from radiotherapy, but the committee agreed that further research was required to determine if the risks of radiotherapy outweighed the benefits in some women.

How the recommendations might affect practice

The committee noted that decisions about postmastectomy radiotherapy after neoadjuvant chemotherapy are currently based on pretreatment investigations, so there will be no change to practice.

Full details of the evidence and the committee's discussion are in evidence review J: neoadjuvant treatment of early and locally advanced breast cancer.

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Lymphoedema

Recommendation 1.12.3

Why the committee made the recommendation

Good evidence showed that there is no increased risk of lymphoedema associated with maintaining exercise levels after axillary intervention, so the committee agreed that people should not restrict or avoid physical activity.

Although the evidence was limited and mixed, the committee concluded that there is no consistent evidence of increased risk of lymphoedema associated with air travel, travel to hot countries, manicures, hot-tub use, sports injuries, or medical procedures on the treated side.

How the recommendation might affect practice

Advice about preventing lymphoedema is already being provided as part of routine care, so there is unlikely to be much change in practice. However, the recommendation will lead to greater consistency in the advice offered. It should also reduce inequality and improve the quality of standard care if people who have had axillary treatment need immunisations or elective procedures.

Full details of the evidence and the committee's discussion are in evidence review B: management of the positive axilla.

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Lifestyle

Recommendations 1.14.1 and 1.14.2

Why the committee made the recommendation

There was evidence that both dietary changes (reducing fat intake and maintaining a healthy weight) and physical activity increase survival in people with invasive breast cancer.

There was some evidence that cancer recurrence is more likely in people who drink more than 3 or 4 alcoholic drinks per week or 6 g of alcohol per day. This equates to approximately 5 units of alcohol per week.

There was no evidence that smoking cessation reduces recurrence of breast cancer, although the view of the committee was that smoking cessation should always be recommended to people with breast cancer.

How the recommendations might affect practice

The committee discussed that many NHS services would already be advising people with breast cancer about the importance of a healthy lifestyle, and how they can make lifestyle changes to reduce the risk of recurrence. The committee agreed that these recommendations will help to direct conversations towards effective lifestyle changes. There will be no impact on resources because these discussions were already happening, and most of the lifestyle changes will be 'self-care' and implemented by patients themselves.

Full details of the evidence and the committee's discussion are in evidence review K: lifestyle.

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Context

This guideline updates and replaces the NICE guideline on early and locally advanced breast cancer (CG80). This is because new evidence was identified in surveillance that could affect recommendations, and has already changed clinical practice in some locations.

People with symptoms that could be caused by breast cancer are referred by their GP to designated breast clinics in local hospitals (see NICE's guideline on suspected cancer: recognition and referral). In addition, eligible women are invited for screening through the NHS Breast Screening Programme (NHSBSP) in England or the Breast Test Wales Screening Programme (BTWSP) in Wales. For most people, whether they are referred following breast screening or after presentation to a GP, diagnosis in the breast clinic is made by triple assessment (clinical assessment, mammography and/or ultrasound imaging, and core biopsy and/or fine needle aspiration cytology). It is best practice to carry out these assessments at the same visit (see NICE's cancer service guideline on improving outcomes in breast cancer).

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

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

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

Groups that are covered

Adults (18 and over) with:

- newly diagnosed invasive adenocarcinoma of the breast of any size (T1–T4), with or without spread to locoregional lymph nodes (N0–N3) and with no distant metastases (M0)
- newly diagnosed ductal carcinoma in situ (DCIS)
- Paget's disease of the breast.

Groups that are not covered

Adults (18 and over) with:

- invasive adenocarcinoma of the breast and distant metastases (clinical or pathological M1)
- rare breast tumours (for example, angiosarcoma, lymphoma)
- benign breast tumours (for example, fibroadenoma)
- phyllodes tumour
- locally recurrent breast cancer or DCIS
- lobular carcinoma in situ (LCIS)
- no personal history of breast cancer and an increased risk of breast cancer due to family history.

Finding more information and resources

You can see everything NICE says on early and locally advanced breast cancer in our interactive flowchart on early and locally advanced breast cancer.

To find out what NICE has said on topics related to this guideline, see our web page on breast cancer.

For full details of the evidence and the guideline committee's discussions, see the evidence reviews. You can also find information about how the guideline was developed, including details of the committee.

NICE has produced tools and resources to help you put this guideline into practice. For general help and advice on putting NICE guidelines into practice, see resources to help you put guidance into practice.

Update information

We have reviewed the evidence and made new recommendations on the diagnosis and treatment of people with early and locally advanced breast cancer. These recommendations are marked [2018].

We have also made some changes without an evidence review:

- Recommendation 1.2.1 now refers to NICE's guideline on patient experience in adult NHS services because specific communications skills training programmes do not take place any more.
- In recommendation 1.2.1, the name of the professional has changed to key worker, per the breast cancer quality standard QS12.
- Recommendation 1.3.3 has been amended because all recurrence rates should be audited, not just for ductal carcinoma in situ (DCIS).
- Recommendation 1.4.6 was partly updated and replaced; the remaining part on biopsy has been retained.
- 'Multidisciplinary team' was added to recommendation 1.6.7 to make it clear this is where the results should be discussed.
- In recommendation 1.1.4, a link has been added to the guideline (CG164) on familial breast cancer, which covers information on genetic testing.
- Recommendation 1.7.2 was amended because the original recommendations had not made clear that premenopausal women (and men) should receive tamoxifen first line, and that it should be used in low-risk postmenopausal women as well as if aromatase inhibitors are not tolerated or contraindicated.
- Recommendation 1.8.4 was amended to distinguish between this recommendation and the new recommendation for T1a/T1b, so it was felt necessary to add 'T1c and above' to this recommendation. The wording of the trastuzumab recommendations have been amended in line with the current summary of product characteristics and the population added to make the recommendation clearer.
- Recommendation 1.9.4 was reworded to exclude those people who were receiving bisphosphonates as adjuvant therapy.

- Recommendation 1.10.9 was changed from 'offer' to 'consider' because it contradicted the new recommendations on margins after surgery for DCIS.
- In recommendation 1.10.7, the word 'adequate' was changed to 'with clear margins'.
- In recommendation 1.10.14, the term 'site of local excision' has been amended to 'tumour bed', and breast-conserving surgery has been removed because this is now covered by additional recommendations.
- In recommendation 1.10.16, the term 'axilla and supraclavicular fossa' has been changed to 'regional lymph nodes'.
- In recommendation 1.10.17, the term 'ALND' has been changed to 'axillary clearance'.
- In recommendation 1.12.12, the guideline committee was aware of new evidence on other selective serotonin reuptake inhibitors (SSRIs) and has amended the wording accordingly, but could not be specific because there was no new evidence review in this guideline update.

These recommendations are marked **[2009, amended 2018]**.

Recommendations marked **[2009]** last had an evidence review in 2009. In some cases, minor changes have been made to the wording to bring the language and style up to date, without changing the meaning.

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