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.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

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 TA107, TA108, TA109, TA112, ES15 and CG80.

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.

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 NICE's information on making decisions about your care.

This guideline uses specific, inclusive language to describe the population groups it covers (for example, women and pregnant people, or trans and non-binary people) except when:

- the evidence for the recommendation has not been reviewed and it is not certain from expert opinion whether it can cover more groups, **or**
- the evidence has been reviewed, but the information available for some groups at the time of development was too limited to make specific recommendations, **or**
- only a very limited number of recommendations have been updated in direct response to new evidence or to reflect a change in practice.

Healthcare professionals should use their clinical judgement when implementing gender-specific recommendations, taking into account the individual's circumstances, needs and preferences, and ensuring all people are treated with dignity and respect throughout their care.

Making decisions using NICE guidelines explains how we use words to show the strength (or certainty) of our recommendations, and has information about prescribing medicines (including off-label use), professional guidelines, standards and laws (including on consent and mental capacity), and safeguarding.

1.1 Preoperative assessment

1.1.1 For people having investigations for early and locally advanced invasive breast cancer:

- perform pretreatment ultrasound evaluation of the axilla, **and**

- if abnormal lymph nodes are identified, perform ultrasound-guided needle sampling. **[2009]**

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

1.1.3 Offer MRI of the breast as part of preoperative assessment to people with invasive breast cancer:

- if the extent of disease is not clear from clinical examination, mammography and ultrasound assessment for planning treatment
- if accurate mammographic assessment is difficult because of breast density
- to assess the tumour size if breast-conserving surgery is being considered for invasive lobular cancer. **[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 the recommendations on genetic testing in the NICE guideline on familial breast cancer). **[2017]**

1.2 Providing information and psychological support

1.2.1 Ensure all people with breast cancer have a named clinical nurse specialist, or other specialist key worker with equivalent skills, to support them throughout diagnosis, treatment and follow-up. **[2009, amended 2018]**

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

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

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

For a short explanation of why the committee made the 2018 recommendations and how they might affect practice, see the rationale and impact section on providing information and psychological support.

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 or DCIS is present at the radial margins ('tumour on ink'; 0 mm). **[2018]**

For a short explanation of why the committee made the 2018 recommendation and how it might affect practice, see the rationale and impact section on surgery to the breast.

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

Further surgery after breast-conserving surgery

1.3.2 Consider further surgery (re-excision or mastectomy, as appropriate) after breast-conserving surgery for invasive cancer with or without DCIS if tumour cells are present within 1 mm of, but not at, the radial margins (greater than 0 mm and less than 1 mm). As part of the decision making:

- discuss the benefits and risks with the person
- take into account:

- the person's circumstances, needs and preferences
- any comorbidities
- tumour characteristics and potential treatments, including the use of radiotherapy (also see radiotherapy after breast-conserving surgery) and other adjuvant therapies. **[2024]**

1.3.3 Consider further surgery (re-excision or mastectomy, as appropriate) after breast-conserving surgery for DCIS without invasive cancer if tumour cells are present within 2 mm of, but not at, the radial margins (greater than 0 mm and less than 2 mm). As part of the decision making:

- discuss the benefits and risks with the person
- take into account:
  - the person's circumstances, needs and preferences
  - any comorbidities
  - tumour characteristics and potential treatments, including the use of radiotherapy (also see radiotherapy after breast-conserving surgery) and other adjuvant therapies. **[2024]**

1.3.4 When discussing the benefits and risks of further surgery, follow the recommendations on:

- enabling patients to actively participate in their care in NICE's guideline on patient experience in adult NHS services, **and**
- communicating risks, benefits and consequences in NICE's guideline on shared decision making. **[2024]**

1.3.5 All breast units should audit their local, regional and distant recurrence rates after treatment, including systematically collecting data on radial margins and demographic information (such as socioeconomic status, age and ethnicity). **[2009, amended 2024]**

For a short explanation of why the committee made the 2024 recommendations and how they might affect practice, see the rationale and impact section on further surgery after breast-conserving surgery.

Full details of the evidence and the committee's discussion are in evidence review N: further surgery after breast-conserving surgery based on tissue margins.

Paget's disease

1.3.6 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 surgery using sentinel lymph node biopsy (SLNB) rather than axillary lymph node clearance to stage the axilla for people with invasive breast cancer if they have:

- no evidence of lymph node involvement on ultrasound, **or**
- a negative ultrasound-guided needle biopsy. **[2009, amended 2023]**

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 routinely perform SLNB for women with a preoperative diagnosis of DCIS

who are having breast-conserving surgery, unless they are considered to be at high risk 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 macrometastasis. **[2018]**

1.4.8 Discuss the benefits and risks of not having 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 to people who only have micrometastases in their sentinel lymph nodes after primary surgery for invasive breast cancer. **[2018]**

1.4.10 Do not offer further axillary treatment to people who have isolated tumour cells in

their sentinel lymph nodes after primary surgery for invasive breast cancer. Classify this as lymph node-negative breast cancer. **[2018]**

For a short explanation of why the committee made the 2018 recommendations and how they might affect practice, see the rationale and impact section on evaluation and management of a positive axillary lymph node.

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

1.5 Breast reconstruction

1.5.1 Offer breast reconstruction to people after they have had mastectomy for breast cancer. **[2023]**

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

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

1.5.4 Offer immediate breast reconstruction to women who have been advised to have a mastectomy, including those who may need radiotherapy, unless they have comorbidities that rule out reconstructive surgery. **[2018, amended 2023]**

1.5.5 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

Category	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
Number and timing of operations	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) Fewer operations may be needed	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) More operations may be needed

Category	Immediate breast reconstruction	Delayed breast reconstruction
Breast reconstruction options available	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 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	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 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
Benefits	Breast shape remains, which may help maintain body image and have subsequent psychological benefits	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

Category	Immediate breast reconstruction	Delayed breast reconstruction
Risks	Surgical complications can occur after any breast reconstruction and will vary by type of procedure and personal risk factors 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	Surgical complications can occur after any breast reconstruction and will vary by type of procedure and personal risk factors 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	No clear differences in satisfaction with completed reconstructions

Category	Immediate breast reconstruction	Delayed breast reconstruction
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

For a short explanation of why the committee made the 2018 recommendations and how they might affect practice, see the rationale and impact section on breast reconstruction.

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

1.6 Diagnostic assessment and adjuvant therapy planning

Predictive factors

1.6.1 Assess the oestrogen receptor (ER), progesterone receptor (PR) and human epidermal growth factor 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]**

For a short explanation of why the committee made the 2018 recommendations and how they might affect practice, see the rationale and impact section on predictive factors.

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

Adjuvant therapy planning

1.6.6 Consider adjuvant therapy after surgery for people with invasive breast cancer, and ensure that recommendations are documented 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 the PREDICT tool, 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.

  Take into account that the potential limitations in versions of PREDICT after 2.0 may differ from those listed here (also see the PREDICT tool frequently asked questions). **[2018, amended 2023]**

For a short explanation of why the committee made the 2018 recommendations and how they might affect practice, see the rationale and impact section on adjuvant therapy planning.

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

Tumour profiling tests to guide adjuvant chemotherapy decisions

The NICE diagnostics guidance on tumour profiling tests provides evidence-based recommendations on tumour profiling tests to guide adjuvant chemotherapy decisions.

1.7 Endocrine therapy

1.7.1 Treat all people with invasive breast cancer with surgery and appropriate systemic therapy, rather than endocrine therapy alone, unless a significant comorbidity means surgery is not suitable for them. **[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 as the initial adjuvant endocrine therapy for postmenopausal women with ER-positive invasive breast cancer who are at medium or high risk of disease recurrence. Offer tamoxifen to women who are at low risk 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]**

For a short explanation of why the committee made the 2018 recommendations and how they might affect practice, see the rationale and impact section on ovarian function suppression.

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

Extended endocrine (hormone) therapy

In June 2023, the use of aromatase inhibitors in recommendations 1.7.6 and 1.7.7 was off-label. See NICE's information on prescribing medicines.

1.7.6 Discuss the benefits and risks of extended endocrine therapy with people who this treatment may be suitable for (see table 2). **[2018, amended 2023]**

1.7.7 Offer extended endocrine therapy (past the 5-year point) with an aromatase inhibitor for postmenopausal women with ER-positive invasive breast cancer who are at medium or high risk of disease recurrence and who have been taking tamoxifen for 2 to 5 years. Medium or high risk may include people who have lymph node-positive breast cancer, with tumours that are T2 or greater and higher grade. **[2018]**

1.7.8 Consider extended endocrine therapy (past the 5-year point) with an aromatase inhibitor for postmenopausal women with ER-positive invasive breast cancer who are at low risk of disease recurrence and who have been taking tamoxifen for 2 to 5 years. Low risk may include people with lymph node-negative breast cancer, with smaller or lower-grade tumours. **[2018]**

1.7.9 Consider extending the duration of tamoxifen therapy for longer than 5 years for people with ER-positive invasive breast cancer. **[2018]**

Table 2 Effects of extended endocrine therapy

Category	**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	People with ER-positive invasive breast cancer	Postmenopausal women with ER-positive invasive breast cancer

Category	Extended tamoxifen therapy (after an initial 5 years of tamoxifen therapy)	Extended endocrine therapy with an aromatase inhibitor (after 5 years of tamoxifen therapy)
Effect on breast cancer recurrence: 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	Evidence shows lower rates of breast cancer recurrence compared with 5 years of tamoxifen therapy in women	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

Category	Extended tamoxifen therapy (after an initial 5 years of tamoxifen therapy)	Extended endocrine therapy with an aromatase inhibitor (after 5 years of tamoxifen therapy)
Side effects: 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) Side effects may differ in men 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	For women, effects on fertility and family planning will continue for additional years as they 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

For a short explanation of why the committee made the 2018 recommendations and how they might affect practice, see the rationale and impact section on extended endocrine therapy.

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

Endocrine therapy for ductal carcinoma in situ

1.7.10 Discuss the benefits and risks (see table 3) of endocrine therapy after breast-conserving surgery for women with ER-positive DCIS. **[2018]**

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

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

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

Category	**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: 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 survival at 5 or 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

Category	Endocrine therapy after breast-conserving surgery for women with ER-positive DCIS
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

For a short explanation of why the committee made the 2018 recommendations and how they might affect practice, see the rationale and impact section on endocrine therapy for DCIS.

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

1.8 Adjuvant chemotherapy for invasive breast cancer

1.8.1 For people with breast cancer where chemotherapy is indicated, offer a regimen that contains both a taxane and an anthracycline. Refer to the summaries of product characteristics for individual taxanes and anthracyclines to check for differences in licensed indications. **[2018, amended 2023]**

1.8.2 Discuss with people the benefits and risks of adding a taxane to anthracycline-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

Refer to the summaries of product characteristics for individual taxanes and anthracyclines to check for differences in licensed indications. **[2018]**

Table 4 Benefits and risks of adding a taxane to anthracycline-containing regimens and comparison of different taxane regimens [2018, amended 2023]

Effect of adding a taxane to an anthracycline-containing regimen	**3-weekly docetaxel**	**Weekly or fortnightly paclitaxel**
Effect on survival: 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	Some evidence for improved outcomes, including reducing the risk of breast cancer returning and increasing the chance of surviving	Some evidence for improved outcomes, including reducing the risk of breast cancer returning and increasing the chance of surviving

Effect of adding a taxane to an anthracycline-containing regimen	3-weekly docetaxel	Weekly or fortnightly paclitaxel
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	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)	8 to 12 weeks

1.8.3 Ensure weekly and fortnightly paclitaxel is available locally, as it is better tolerated than 3-weekly docetaxel, particularly in people with comorbidities. **[2018, amended 2023]**

For a short explanation of why the committee made the 2018 recommendations and how they might affect practice, see the rationale and impact section on adjuvant chemotherapy for invasive breast cancer.

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

Biological therapy

1.8.4 Offer adjuvant trastuzumab for people with T1c and above HER2-positive invasive breast cancer. Give this at 3-week intervals for 1 year in combination with surgery, chemotherapy, endocrine therapy and radiotherapy, as appropriate. **[2009, amended 2023]**

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

For a short explanation of why the committee made the 2018 recommendation and how it might affect practice, see the rationale and impact section on biological therapy.

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

1.8.6 Use trastuzumab with caution in people with HER2-positive invasive breast cancer if they 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]**

1.9 Bisphosphonate therapy

Adjuvant bisphosphonate therapy

In June 2023, the use of bisphosphonates (zoledronic acid or sodium clodronate) in recommendations 1.9.1 and 1.9.2 was off-label. See NICE's information on prescribing medicines.

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

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

For a short explanation of why the committee made the 2018 recommendations and how they might affect practice, see the rationale and impact section on adjuvant bisphosphonate therapy.

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

Bone health

1.9.4 Offer a baseline dual-energy X-ray absorptiometry (DEXA) scan to assess bone mineral density 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 people with invasive breast cancer who are receiving tamoxifen alone. **[2009, amended 2023]**

1.9.6 Offer bisphosphonates to women identified by algorithms 1 and 2 in the guidance for the management of breast cancer treatment-induced bone loss: a consensus position statement from a UK expert group (2008; this guidance is not NICE-accredited). **[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]**

For a short explanation of why the committee made the 2018 recommendations and how they might affect practice, see the rationale and impact section on radiotherapy techniques.

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

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 If partial-breast radiotherapy (see recommendation 1.10.4) may be suitable for a woman, discuss the benefits and risks with them and reach a shared decision on its use. Topics to cover include 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, amended 2023]**

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

1.10.7 Consider not using 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 not using radiotherapy (see recommendation 1.10.7), discuss the benefits and risks with the woman (see 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 low-risk group described in recommendation 1.10.7

Category	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

Category	Radiotherapy	No radiotherapy
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. Discuss the possible benefits and risks of radiotherapy (also see the section on surgery to the breast) and make a shared decision about its use. **[2009]**

For a short explanation of why the committee made the 2018 recommendations and how they might affect practice, see the rationale and impact section on radiotherapy after breast-conserving surgery.

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

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 of local recurrence (for example, most people who have lymph node-negative breast cancer). **[2018, amended 2023]**

For a short explanation of why the committee made the 2018 recommendations and how they might affect practice, see the rationale and impact section on radiotherapy after mastectomy.

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

Dose fractionation for external beam radiotherapy

1.10.13 Offer 26 Gy in 5 fractions over 1 week for people with invasive breast cancer having partial-breast, whole-breast or chest-wall radiotherapy, without regional lymph node irradiation, after breast-conserving surgery or mastectomy. **[2023]**

1.10.14 Consider 40 Gy in 15 fractions over 3 weeks for people with invasive breast cancer having partial-breast, whole-breast or chest-wall radiotherapy, without regional lymph node irradiation, after breast-conserving surgery or mastectomy when they:

- have a diagnosis that increases sensitivity to radiotherapy, **or**
- have had implant-based reconstruction, **or**
- have any other factor that could mean having radiotherapy over 3 weeks is more acceptable (such as high BMI or fibromyalgia). **[2023]**

1.10.15 When discussing the benefits and risks of the 2 regimens, follow the recommendations on:

- enabling patients to actively participate in their care in the NICE guideline on patient experience in adult NHS services, **and**
- communicating risks, benefits and consequences in the NICE guideline on shared decision making. **[2023]**

1.10.16 Offer 40 Gy in 15 fractions over 3 weeks for people with invasive breast cancer having regional lymph node irradiation, with or without whole-breast or chest-wall radiotherapy, after breast-conserving treatment or mastectomy. **[2023]**

For a short explanation of why the committee made the 2023 recommendations and how they might affect practice, see the rationale and impact section on dose fractionation of external beam radiotherapy.

Full details of the evidence and the committee's discussion are in evidence review M: effectiveness of different external beam hypofractionation radiotherapy regimens in people with early-stage or locally advanced invasive breast cancer.

Breast boost following breast-conserving surgery

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

1.10.18 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

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

1.10.20 Do not offer people with invasive breast cancer adjuvant radiotherapy to the axilla after axillary clearance. **[2009, amended 2023]**

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

1.10.22 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]**

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

For a short explanation of why the committee made the 2018 recommendation and how it might affect practice, see the rationale and impact section on radiotherapy to nodal areas.

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

Intraoperative radiotherapy

1.10.24 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 guidance 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]**

For a short explanation of why the committee made the 2018 recommendations and how they might affect practice, see the rationale and impact section on neoadjuvant chemotherapy.

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

Neoadjuvant chemotherapy regimens

In June 2023, the use of platinums in recommendations 1.11.4 and 1.11.5 was off-label. See NICE's information on prescribing medicines.

1.11.4 For people with ER/PR/HER2-negative (triple-negative) invasive breast cancer, consider a neoadjuvant chemotherapy regimen that contains both a platinum and an anthracycline. **[2018]**

1.11.5 Discuss the benefits and risks of adding a platinum to an anthracycline-containing neoadjuvant chemotherapy regimen (see table 6), and in particular 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

Category	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

Category	Effect of adding a platinum to anthracycline-containing (with or without taxane) neoadjuvant chemotherapy
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 axilla, compared with anthracycline-based (with or without taxane) neoadjuvant chemotherapy
Effect on survival	No increase in overall survival with platinum-based chemotherapy
Side effects: 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

For a short explanation why the committee made the 2018 recommendations and how they might affect practice, see the rationale and impact section on neoadjuvant chemotherapy regimens.

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

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 (see table 7). **[2018]**

Table 7 Benefits and risks of neoadjuvant endocrine therapy compared with neoadjuvant chemotherapy for women with ER-positive/HER2-negative breast cancer

Category	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

Category	Neoadjuvant endocrine therapy	Neoadjuvant chemotherapy
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

Category	Neoadjuvant endocrine therapy	Neoadjuvant chemotherapy
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

For a short explanation of why the committee made the 2018 recommendations and how they might affect practice, see the rationale and impact section on neoadjuvant endocrine therapy.

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

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]**

For a short explanation of why the committee made the 2018 recommendations and how they might affect practice, see the rationale and impact section on radiotherapy after neoadjuvant chemotherapy.

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

1.12 Complications of local treatment and menopausal symptoms

Lymphoedema

1.12.1 Inform people with breast cancer about lymphoedema and their risk of developing it after treatment with surgery and radiotherapy (see recommendation 1.12.2). Give them relevant written information before treatment to take away and refer back to. **[2009]**

1.12.2 When informing people with breast cancer about the risk of developing lymphoedema, advise them that:

- lymphoedema can occur in the arm, breast or chest wall
- 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, amended 2023]**

1.12.3 Give people who have had treatment for breast cancer advice on how to reduce the risk of infection that may cause or exacerbate lymphoedema. **[2009]**

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

For a short explanation of why the committee made the 2018 recommendation and how it might affect practice, see the rationale and impact section on lymphoedema.

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

Arm and shoulder mobility

1.12.5 Ensure breast care units have documented local guidelines in place for postoperative physiotherapy that have been agreed with the physiotherapy department. Guidelines should cover:

- details of the upper limb exercises to be carried out after surgical or radiotherapy interventions
- situations where the exercises should be tailored for individual circumstances and needs
- who should give information and instructions, and at what points in the person's care this should happen
- how healthcare staff can best deliver information about the exercises. **[2023]**

1.12.6 Give people who are going to have surgery or radiotherapy for breast cancer instructions and information on upper limb exercises before their treatment begins:

- explain the benefits of doing the exercises
- explain when the exercises should be started
- ensure the information is in a format suitable for the person to take away to refer to later
- answer any questions the person may have on the exercises, or how to perform them
- give details about who to contact if more information is needed.

  Also see the section on communication in the NICE guideline on patient experience in adult NHS services. **[2023]**

1.12.7 Preoperatively identify people who are having surgery for breast cancer as being at high risk of developing shoulder problems if they have any of the following factors:

- any pre-existing shoulder conditions, such as:
  - history of shoulder surgery
  - shoulder trauma injury (fracture or shoulder dislocation)
  - frozen shoulder
  - osteoarthritis or rheumatoid arthritis affecting the shoulder
  - non-specific shoulder pain
  - stiffness
  - decreased function
- their BMI is over 30 kg/m^2
- they have axillary node clearance planned

- they have radiotherapy to the axilla or supraclavicular nodes planned. **[2023]**

1.12.8 After surgery, if a person with breast cancer needs previously unplanned axillary node clearance or radiotherapy to the axilla or supraclavicular nodes, identify them as being at high risk. **[2023]**

1.12.9 Offer supervised support when performing upper limb exercises to people who have been identified as being at high risk of developing shoulder problems after surgery for breast cancer (see recommendation 1.12.7 for assessment). **[2023]**

1.12.10 Consider supervised support when performing upper limb exercises for people who:

- are having surgery and have not been identified as being at high risk of developing shoulder problems (as defined by the criteria in recommendation 1.12.7), but who may still benefit from supervised support **or**
- are having radiotherapy without surgery. **[2023]**

1.12.11 Ensure supervised support for upper limb exercises:

- is available as either individual, group or virtual support, depending on the person's circumstances, needs and preferences
- is tailored to the person's needs (for example, modifying exercises for people with more complex needs)
- includes checking that the person is performing the activity correctly
- is delivered by physiotherapy staff members or other appropriately trained allied health professionals. **[2023]**

1.12.12 Refer people to the physiotherapy department for individual assessment and treatment if they report a persistent reduction in arm and shoulder mobility after breast cancer surgery or radiotherapy. **[2023]**

For a short explanation of why the committee made the 2023 recommendations and how they might affect practice, see the rationale and impact section on arm and shoulder mobility.

Full details of the evidence and the committee's discussion are in evidence review L: strategies for reducing arm and shoulder problems after breast cancer surgery or radiotherapy.

Menopausal symptoms

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

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

1.12.15 Do not routinely offer HRT (including oestrogen/progestogen combination) to women with menopausal symptoms and a history of breast cancer. **[2009, amended 2023]**

In June 2023, this was an off-label use of HRT, and HRT is contraindicated in women with a history of breast cancer. See NICE's information on prescribing medicines.

1.12.16 In exceptional circumstances, offer HRT to women with severe menopausal symptoms and a history of breast cancer after a discussion of the associated risks. **[2009, amended 2023]**

In June 2023, this was an off-label use of HRT, and HRT is contraindicated in women with a history of breast cancer. See NICE's information on prescribing medicines.

1.12.17 Consider selective serotonin reuptake inhibitor (SSRI) antidepressants for women with breast cancer for relieving menopausal symptoms, particularly hot flushes, but not for those taking tamoxifen. For guidance on safe prescribing of

antidepressants (such as SSRIs) and managing withdrawal, see NICE's guideline on medicines associated with dependence or withdrawal symptoms. **[2009, amended 2018]**

In June 2023, this was an off-label use of SSRIs. See NICE's information on prescribing medicines.

1.12.18 Do not offer soy (isoflavone), red clover, black cohosh, vitamin E or magnetic devices to treat vasomotor symptoms in women with breast cancer. **[2009, amended 2023]**

1.13 Follow-up

Follow-up imaging

1.13.1 Offer annual mammography for 5 years to all people who have had or are being treated for breast cancer, including DCIS. For women, continue annual mammography past 5 years until they enter the NHS Breast Screening Programme (NHSBSP) in England or the Breast Test Wales Screening Programme (BTWSP) in Wales. **[2009, amended 2023]**

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

1.13.3 Do not routinely use ultrasound or MRI for post-treatment surveillance in people who have had treatment for invasive breast cancer or DCIS. **[2009, amended 2023]**

Clinical follow-up

1.13.4 Ensure all people who have had treatment for breast cancer have an agreed, written care plan, recorded in their notes by a named healthcare professional (or professionals) from the multidisciplinary team. Give a copy to the person and to their GP. The plan should include:

- designated named healthcare professionals
- dates for review of any adjuvant therapy
- details of surveillance mammography
- signs and symptoms to look out for and seek advice on
- contact details for immediate referral to specialist care
- contact details for support services, for example, support for people with lymphoedema. **[2009, amended 2023]**

1.14 Lifestyle

1.14.1 Advise people who have had or are being treated for 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
- 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 tobacco: preventing uptake, promoting quitting and treating dependence. **[2018]**

For a short explanation of why the committee made the 2018 recommendations and how they might affect practice, see the rationale and impact section on lifestyle.

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

Terms used in this guideline

Upper limb exercises

Upper limb exercises predominantly focus on gentle shoulder range-of-movement exercises and stretches aimed at regaining full and pain-free range of movement of the shoulder following breast cancer surgery and/or radiotherapy. The term can also refer to exercises that progress onto strengthening the shoulder and arm.

Recommendations for research

The guideline committee has made the following 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? **[2018]**

For a short explanation of why the committee made the recommendation for research, see the rationale section on surgery to the breast.

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

2 Adjuvant bisphosphonate therapy

Which groups of people with early and locally advanced breast cancer would benefit from the use of adjuvant bisphosphonates? **[2018]**

For a short explanation of why the committee made the recommendation for research, see the rationale section on adjuvant bisphosphonate therapy.

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

3 Breast reconstruction

What are the long-term outcomes for breast reconstruction in women having radiotherapy to the chest wall? **[2018]**

For a short explanation of why the committee made the recommendation for research, see the rationale section on breast reconstruction.

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

4 Neoadjuvant endocrine therapy in premenopausal women

Is neoadjuvant endocrine therapy safe in premenopausal women with early breast cancer? **[2018]**

For a short explanation of why the committee made the recommendation for research, see the rationale section on neoadjuvant endocrine therapy.

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

5 Neoadjuvant endocrine therapy in postmenopausal women

Is there a benefit for neoadjuvant endocrine therapy in postmenopausal women with early breast cancer? **[2018]**

For a short explanation of why the committee made the recommendation for research, see the rationale section on neoadjuvant endocrine therapy.

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

6 Neoadjuvant treatment

What are the indications for postmastectomy radiotherapy after neoadjuvant chemotherapy? **[2018]**

For a short explanation of why the committee made the recommendation for research, see the rationale section on radiotherapy after neoadjuvant chemotherapy.

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

7 Strategies to reduce arm and shoulder problems

What is the most effective and cost-effective way of delivering the intervention (for example, type of physiotherapy or exercise, mode of delivery, number of sessions) to reduce arm and shoulder problems after breast cancer surgery or radiotherapy, and what is the acceptability of the intervention for different groups, such as:

- women, men, trans people and non-binary people
- people from minority ethnic family backgrounds
- people with learning disabilities or cognitive impairment, or physical disabilities, or both
- neurodiverse people? **[2023]**

For a short explanation of why the committee made the recommendation for research, see the rationale section on arm and shoulder mobility.

Full details of the evidence and the committee's discussion are in evidence review L: strategies for reducing arm and shoulder problems after breast cancer surgery or radiotherapy.

8 Adherence and satisfaction for interventions to

reduce arm and shoulder problems

What is the adherence to, and satisfaction with, different intervention formats (for example, individual, group, virtual, and face to face) to reduce arm and shoulder problems after breast cancer surgery or radiotherapy, and what is the impact of greater adherence on effectiveness for different groups, such as:

- women, men, trans people and non-binary people
- people from minority ethnic family backgrounds
- people with learning disabilities or cognitive impairment, or physical disabilities, or both
- neurodiverse people? **[2023]**

For a short explanation of why the committee made the recommendation for research, see the rationale section on arm and shoulder mobility.

Full details of the evidence and the committee's discussion are in evidence review L: strategies for reducing arm and shoulder problems after breast cancer surgery or radiotherapy.

9 Effectiveness of 26 Gy in 5 fractions over 1 week regimen in people receiving breast reconstruction

What is the effectiveness of radiotherapy given in 26 Gy in 5 fractions over 1 week compared with 40 Gy in 15 fractions over 3 weeks in people with early or locally advanced invasive breast cancer who are offered breast reconstruction? **[2023]**

For a short explanation of why the committee made the recommendation for research, see the rationale section on dose fractionation of external beam radiotherapy.

Full details of the evidence and the committee's discussion are in evidence review M: effectiveness of different external beam hypofractionation radiotherapy regimens in people with early-stage or locally advanced invasive breast cancer.

10 Effectiveness of 26 Gy in 5 fractions over 1 week regimen in people receiving nodal irradiation

What is the effectiveness of radiotherapy given in 26 Gy in 5 fractions over 1 week compared with 40 Gy in 15 fractions over 3 weeks in people with early or locally advanced invasive breast cancer who are also offered nodal irradiation? **[2023]**

For a short explanation of why the committee made the recommendation for research, see the rationale section on dose fractionation of external beam radiotherapy.

Full details of the evidence and the committee's discussion are in evidence review M: effectiveness of different external beam hypofractionation radiotherapy regimens in people with early-stage or locally advanced invasive breast cancer.

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

Recommendations 1.2.3 and 1.2.4

Why the committee made the recommendations

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.

People having treatment for breast cancer should be advised about options for preserving their fertility, so the existing NICE guideline on this topic was cross-referred to.

How the recommendations 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.

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

Recommendation 1.3.1

Why the committee made the recommendation

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.

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 and made a recommendation for research on the optimum tumour-free margin width after surgery to the breast.

How the recommendation might affect practice

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

Return to recommendation

Further surgery after breast-conserving surgery

Recommendations 1.3.2 to 1.3.5

Why the committee made the recommendations

The committee agreed that the best choice for radial margin size would be a balance between the need for further surgery (to reduce the risk of local recurrence and maximise overall survival) and maintaining good levels of patient satisfaction. This balance also needs to take into account the potential harms of further surgery, and possible need for other treatments to take priority over further surgery. Because of the way the evidence was reported in the included studies, the committee discussed the evidence on radial margins after breast-conserving surgery separately for people who had invasive breast

cancer with or without DCIS and for people who had DCIS only. Most of the data was for local recurrence, with some for distant recurrence and very limited data for overall survival or breast-cancer-specific survival. There was no evidence on patient-reported outcomes or quality of life. Therefore, the committee based most of their discussion on the evidence for local recurrence, and used their personal and clinical experience to consider the perspectives and preferences of people who have breast cancer.

The committee discussions focused on whether a radial margin of 1 mm or 2 mm should be the cut-off for further surgery. The committee agreed that when the tumour is at 0 mm, this balance is strongly in favour of further surgery to try to ensure the full tumour is removed, so the existing recommendation to offer further surgery was retained without reviewing the evidence. For people with invasive breast cancer with or without DCIS, the evidence showed that the risk of local recurrence was higher with radial margins of greater than 0 mm to less than 1 mm compared with greater than or equal to 1 mm. This was also the case for local recurrence when radial margins of greater than 0 mm to 2 mm were compared with greater than 2 mm. However, the evidence could not differentiate between greater than 1 mm to 2 mm compared with greater than 2 mm. The committee also noted that the incidence of local recurrence has decreased because of advances in breast cancer care.

Taking this into account with the evidence for local recurrence, the committee did not think that recommending a margin of 1 mm, rather than 2 mm, would lead to a substantially increased risk of local recurrence. Additionally, they agreed that for many people, a margin of 1 mm is likely to be preferable over a more cautious approach with a margin of 2 mm because the smaller margin is likely to achieve better breast preservation and result in fewer additional surgeries. They noted that repeated surgeries negatively affect breast appearance, and this can have a negative effect on the person's self-esteem and view of themselves. They are also traumatic for the person involved and can lead to stress, infections, pain, complications associated with recovery from the anaesthetic and operation, and negatively affect their everyday life. As a result, the committee agreed that further surgery should be considered for people who had breast-conserving surgery for invasive breast cancer with or without DCIS if tumour cells are present within 1 mm of the radial margins.

For DCIS only, the limited evidence was of moderate to very low quality, and the committee was not confident of the differences in effect between a margin of less than, or greater than, 2 mm on local recurrence. As a result, they decided to retain the threshold of 2 mm from the existing recommendation when considering further surgery for this

population. The committee did not make a recommendation for research for this group because they were aware of new studies already underway that could inform this decision in the future.

As well as thinking about the potential clinical benefits of further surgery, the committee acknowledged the importance of taking the person's circumstances, needs and preferences into account as part of the decision-making process. This is intended to help ensure that any barriers to particular treatment options are considered and addressed where possible. They recommended that there should be a discussion with the person about the benefits of surgery, such as reducing the risk of recurrence, as well as risks, such as infection and complications. The committee also agreed other clinical factors, such as tumour characteristics and potential treatments, should be taken into account. They referred to the NICE guidelines on shared decision making and patient experience to help inform these discussions.

The committee noted that, in their experience, the existing recommendation about auditing recurrence is not uniformly applied and that the information recorded does not necessarily include the radial margin. They therefore expanded the recommendation to highlight factors that they thought should be recorded in addition to recurrence. The committee was also aware of a new National Audit of Primary Breast Cancer that may improve recording of this information.

The committee noted that there was no evidence for people receiving neoadjuvant hormone therapy or biological treatments and very little evidence for people receiving neoadjuvant chemotherapy, and that the quality of this evidence was very low. Therefore, they could not make a specific recommendation for this group. However, they agreed that the evidence for people who did not have neoadjuvant therapy could be extrapolated to this group and that the recommendation for people with invasive breast cancer with or without DCIS could apply to them as well.

How the recommendations might affect practice

It is not expected that the recommendation for people with invasive breast cancer will increase resource use since it is likely that fewer people will have further surgery given the reduction in margin size. The recommendations should also encourage standardisation of practice in relation to radial margins for invasive breast cancer with or without DCIS across the UK. The recommendations for DCIS retain the existing radial margins and are therefore not expected to change practice or resource use.

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, so 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.

Return to recommendations

Breast reconstruction

Recommendations 1.5.2 to 1.5.5

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. So, they made a recommendation for research on long-term outcomes for breast reconstruction in women having radiotherapy to the chest wall.

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).

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 factor 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, so may lead to a small cost saving.

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.

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 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.

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.

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.

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.

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 with 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, so the impact on current practice would be minor and unlikely to require a substantial increase in resources.

Return to recommendation

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. So, they made a recommendation for research on groups of people who would benefit from the use of 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.

Return to recommendations

Radiotherapy techniques

Recommendations 1.10.1 and 1.10.2

Why the committee made the recommendations

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.

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 recommendations might affect practice

Using a radiotherapy technique that minimises the dose to the lung and heart 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.

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.

Return to recommendations

Radiotherapy after breast-conserving surgery

Recommendations 1.10.3 to 1.10.8

Why the committee made the recommendations

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.

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

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.

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.

Return to recommendations

Radiotherapy after mastectomy

Recommendations 1.10.10 to 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.

Return to recommendations

Dose fractionation of external beam radiotherapy

Recommendations 1.10.13 to 1.10.16

Why the committee made the recommendations

The committee noted that most centres use regimens of either 40 Gy in 15 fractions or 26 Gy in 5 fractions. However, there was variation between centres in which external beam hypofractionation regimen they used.

The evidence compared a number of different external beam hypofractionation regimens, but the committee focused on the evidence from 2 randomised controlled trials (RCTs) that compared clinical effectiveness and safety, and a cost-effectiveness analysis, of the 2 hypofractionation regimens that are established in current practice (40 Gy in 15 fractions over 3 weeks and 26 Gy in 5 fractions over 1 week). High-quality to very low-quality evidence showed that the effects of both external beam hypofractionation regimens were comparable, with no clinically important differences between treatment arms for all-cause mortality, breast cancer-related mortality or disease recurrence. Economic evidence showed the 26 Gy in 5 fractions as an effective use of NHS resources compared with 40 Gy in 15 fractions and supported its use in current practice. In addition, the committee noted that in their experience, most people preferred to attend radiotherapy appointments over the course of 1 week rather than over 3 weeks for practical reasons related to fewer trips to the hospital (for example, reduced travelling time and costs, less time off work or from caring responsibilities). The committee recognised how the COVID-19 pandemic had also impacted current practice and had accelerated the change to implement the shorter 26 Gy in 5 fractions regimen.

The evidence showed that there was a higher incidence of outcomes related to clinician-assessed adverse events at 5 years and quality-of-life measurements (related to harder or firmer breasts) for people who were given 26 Gy in 5 fractions compared with 40 Gy in 15 fractions. However, with the exception of a quality-of-life outcome related to swollen breasts, the differences in effect between the 2 regimens were not clinically significant. The committee agreed that in their experience, 26 Gy in 5 fractions is widely accepted by people, despite the small risk of increased adverse events. After taking into account the benefits of a shorter regimen and the impact of the adverse events, the committee recommended the use of 26 Gy in 5 fractions for people having partial-breast, whole-breast or chest-wall radiotherapy, without nodal irradiation, after breast-conserving surgery or mastectomy.

The committee noted that the evidence presented was from populations who were receiving whole-breast radiotherapy. There was no evidence for people who are at lower risk of disease recurrence than those included in the evidence base and who are offered partial-breast radiotherapy because of their reduced risk. However, the committee agreed that, considering the already lower risk for this population, the findings of 26 Gy in 5 fractions in the higher-risk population could be extrapolated to also cover the lower-risk population. The committee also noted that the decision over whether someone has partial-breast or whole-breast radiotherapy can change based on clinical judgement and assessment of the treatment area. As such, the committee agreed that if partial-breast radiotherapy were excluded, the recommendations would not be in line with current practice and may disadvantage a large group of people.

The committee recognised that there may be circumstances when 40 Gy in 15 fractions would be more suitable than 26 Gy in 5 fractions. For example, the committee noted that, in their clinical experience, some groups of people, such as those with a high BMI or fibromyalgia, may experience a greater number of acute adverse events from the 5-fraction regimen (for example, skin reactions, breast oedema or pain). Therefore, some people may prefer the 15-fraction regimen. The committee also noted that the number of people in the studies who had undergone breast reconstruction surgery was small, and it was difficult to determine the most effective hypofractionation regimen for this group. The 15-fraction regimen may also be used for those whose dosimetry is outside that used in the FAST-Forward trial. The committee highlighted the importance of shared decision making for these groups and ensuring that people are aware of the benefits and risks of each treatment option. As such, the committee made a recommendation that 40 Gy in 15 fractions over 3 weeks should be considered for some groups of people, and that its use should be agreed between the person and their care team.

The committee discussed the eligibility criteria for some of the trials in the evidence and noted that people who received nodal radiotherapy were excluded from the main study populations. They highlighted that there are particular concerns around adverse effects such as lymphoedema for people who received regional lymph node irradiation. The committee acknowledged that future trials and the FAST-Forward nodal sub-study results may address some of these concerns, but until further evidence is available the 40 Gy in 15 fractions regimen should continue to be used for this group.

There was limited evidence comparing the 2 hypofractionation regimens in people having breast reconstruction or having regional lymph node irradiation. As such, the committee developed recommendations for research on people having breast reconstruction

(including autologous breast reconstruction, but particularly implant-based reconstruction) and people having regional lymph node irradiation. These should provide clinicians with an increased understanding of how effective the 26 Gy in 5 fractions regimen is for these groups in future.

How the recommendations might affect practice

The recommendations may reduce variation in practice, with most people being offered 26 Gy in 5 fractions rather than 40 Gy in 15 fractions. This is already current practice in many centres and will not have a major impact for those centres. In those centres where 26 Gy in 5 fractions is not yet current practice, there will be significant cost savings and capacity will be released for more appointments. For places where 40 Gy in 15 fractions is used more routinely, these recommendations may increase the number of people who are offered 26 Gy over 5 fractions. This will reduce the treatment duration and the costs associated with treatment.

Return to recommendations

Radiotherapy to nodal areas

Recommendation 1.10.23

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.

Return to recommendation

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 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.

Return to recommendations

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 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, as well as 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% to 40% of people receiving neoadjuvant chemotherapy may be affected by the recommendations.

Return to recommendations

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. So, they made recommendations for research on the safety of neoadjuvant endocrine therapy in premenopausal women and postmenopausal women with early breast cancer.

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.

Return to recommendations

Radiotherapy after neoadjuvant chemotherapy

Recommendations 1.11.10 to 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. So, they made a recommendation for research on the indications for postmastectomy radiotherapy after neoadjuvant chemotherapy.

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.

Return to recommendations

Lymphoedema

Recommendation 1.12.2

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.

Return to recommendation

Arm and shoulder mobility

Recommendations 1.12.5 to 1.12.12

Why the committee made the recommendations

The committee noted there was very little high-quality evidence for any of the outcomes, and most of the evidence was low to very low quality. The committee agreed that they did not feel confident in making recommendations based on low-quality evidence from mainly single studies. Therefore, they used their clinical knowledge and experience alongside high-quality evidence from 1 UK-based RCT to support their decision making. This evidence showed improved outcomes with a physiotherapy-led structured supervised

exercise programme in addition to usual care for reduction of pain, quality-of-life improvement and adherence to arm and shoulder exercises in people with a higher risk of developing shoulder problems. The trial provided all participants with information leaflets about exercises to help with arm and shoulder mobility after breast cancer surgery. This reflects standard practice in the UK, and the committee agreed it was important to reflect this advice in the recommendations. The recommendations also highlight that instructions on upper limb exercises and information should be discussed, explained and clarified with the person before radiotherapy begins, as the exercises should have been well established before starting treatment. The committee recommended that this should also happen before surgery.

The committee were aware that instructions on upper limb exercises are not always given out by someone who is a specialist in physiotherapy (for example, breast care nurses), so they also recommended that breast care units have documented local guidelines in place that include details about who and how to deliver this information effectively. They thought it was important that the information included details on when the exercises should be started. For most people, this will be the day after surgery, but it may be later for others, such as those who have certain surgical procedures (for example, free flap reconstruction or implant reconstruction) where exercising the day after surgery could interfere with their recovery. Exercises should be tailored to each person based on their needs (for example, comorbidities and side effects of cancer treatment), but for the majority of patients, a standard programme of upper limb exercises will be suitable. The committee also agreed it was important that instructions on upper limb exercises should be available in other formats to be accessible to people with different needs (for example, video or large print and various languages). There are already recommendations on communication in the NICE guideline on patient experience in adult NHS services, so a link to this was included as part of the recommendation.

Based on the effectiveness of the intervention in the UK-based trial, the committee agreed that people who met the same criteria as those included in the trial should be identified as being at higher risk of developing shoulder problems. These people should then be offered supervised support to apply the exercises. The baseline shoulder identification of someone as high risk of developing shoulder problems could be done by a member of the clinical team (for example, a clinical nurse specialist) and could be done by looking at a person's medical history and asking the person if they have experienced any of the issues listed in the recommendation (for example, asking if they have stiffness of their shoulder or if the function of their shoulder is reduced). The evidence did not specify that these risk factors were only relevant to the affected side and the committee noted that people

should be considered at high risk if they have any of the pre-existing shoulder conditions in the contralateral side. It was also highlighted that for most people radiotherapy to the axilla or supraclavicular nodes is decided before surgery. However, for some people this may be decided after postoperative pathology review. For this reason, they recommended that people who are identified as needing radiotherapy to the axilla or supraclavicular nodes after surgery should also be considered as being at higher risk of developing shoulder problems. This ensures that people would not miss out from supervised support if the need for radiotherapy was not identified before surgery.

The committee also agreed that, in their experience, other people having surgery for breast cancer who did not meet the high-risk criteria in the recommendations could benefit from supervised support. This includes, for example, people with learning or sensory disabilities, which could adversely affect their ability to carry out exercises without supervision and make them more likely to develop shoulder problems as a result. It also includes people having breast cancer surgery who have side effects from additional cancer treatments or who have other commonly performed adjunct surgeries in addition to breast cancer surgery, as well as people who are having radiotherapy without surgery.

Based on their experience, the committee recommended that supervised support should be delivered by a physiotherapy staff member or other appropriately trained allied health professional (for example, an occupational therapist). This should include checking the performance of the exercises and correcting them as needed. The committee agreed that people may not feel confident in translating written exercise instructions into physical movement, so would benefit from having advice on whether they are doing them correctly. This support also allows people who might be experiencing difficulties with both the exercises and with shoulder function to be identified early after radiotherapy or surgery. It will also ensure that people are able to receive the full benefit from the exercises, and may increase adherence if someone is confident they are doing the exercises correctly.

The committee also agreed supervised exercises and physiotherapy support should be available in different formats (for example, virtual or group sessions), and be tailored to individual circumstances and needs (for example, mental health and learning needs) to help with adherence. There was no evidence about interventions delivered virtually, but the committee agreed to recommend this option as it may help to reduce health inequalities and address access options for people where other interventions are not locally available. The committee were aware that some people may not be able to access virtual services for a range of reasons, such as a lack of access to suitable devices, living in areas of poor connectivity and difficulties with using the technology. However, including

virtual services in the recommendations should not provide barriers to these people accessing support, as they can be given the option of face-to-face sessions. The committee also highlighted that face-to-face physiotherapy may be more beneficial for people with complex needs or those at higher risk (for example, people from minority ethnic family backgrounds, people with disabilities, neurodiverse people, those who experience physical difficulties with recovery or rehabilitation) because they might need specific instructions and feedback.

The committee were mindful that, while their experience shows that virtual interventions are beneficial, there is a lack of evidence for this and that there was no evidence on whether the format of the intervention (individual, group, virtual, and face to face) impacted adherence or satisfaction. Therefore, the committee took this into account when making recommendations for research to cover this gap in the evidence.

There was limited, low-quality evidence on long-term outcomes and no evidence on outcomes for different population subgroups, such as people from minority ethnic family backgrounds, disabled people and neurodiverse people. The committee also noted that lower-quality evidence comparing interventions was not conclusive. The committee discussed the importance of understanding the most effective and cost-effective way of delivering the intervention (for example, type of physiotherapy or exercise, mode of delivery, number of sessions) and the acceptability of such intervention for different populations, and made a recommendation for research on the most effective and cost-effective way of delivering the intervention to address this gap in the evidence.

The committee also recommended that people should be referred to the physiotherapy department if they report a persistent reduction in arm and shoulder mobility after breast cancer treatment. This allows people to continue to seek support if it is needed. The committee noted that the recommendation for research into adherence to, and satisfaction with, different intervention formats will gather evidence about the long-term effects of strategies to reduce arm and shoulder problems, and this may reduce the number of people who have to be referred to the physiotherapy department in future.

How the recommendations might affect practice

There may be an increase in the number of people having supervised exercise or physiotherapy support after breast cancer surgery or before radiotherapy. However, if this could be delivered virtually (individual or group), it is likely to have a lower impact on NHS resources than in-person 1-to-1 sessions and could free up resources for face-to-face

interventions for those for whom virtual services are not appropriate or if there are barriers to them accessing virtual services.

Return to recommendations

Lifestyle

Recommendations 1.14.1 and 1.14.2

Why the committee made the recommendations

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.

Return to recommendations

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 to 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 to T4), with or without spread to locoregional lymph nodes (N0 to 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 or 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 committee details

To find NICE guidance on related topics, including guidance in development, see the NICE topic 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 our guidelines into practice, see resources to help you put guidance into practice.

Update information

January 2024: We have reviewed the evidence and have updated and made new recommendations on further surgery after breast-conserving surgery. These recommendations are marked **[2024]** or **[2009, amended 2024]**.

June 2023: We have reviewed the evidence and made new recommendations and recommendations for research on dose fractionation for external beam radiotherapy. These recommendations are marked **[2023]**.

We have also made some changes without an evidence review:

- We have updated some wording to bring the language and style up to date, without changing the meaning.
- We have updated some recommendations to bring them in line with current terminology and practice.
- We have combined, clarified or reworded some recommendations to make them clearer and to improve ease of reading.

These recommendations are marked **[2008, amended 2023]** and **[2018, amended 2023]**.

Recommendations marked **[2009]**, **[2017]**, **[2018]** and **[2009, amended 2018]** last had an evidence review in 2009, 2017 and 2018, respectively. In some cases, minor changes have been made to the wording to bring the language and style up to date, without changing the meaning.

April 2023: We have reviewed the evidence and made new recommendations and recommendations for research on arm and shoulder mobility. These recommendations are marked **[2023]**.

July 2018: 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:

- In recommendation 1.1.4, a link has been added to NICE's guideline on familial breast cancer, which covers information on genetic testing.
- Recommendation 1.3.5 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.
- 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.
- In recommendation 1.10.7, the word 'adequate' was changed to 'with clear margins'.
- Recommendation 1.10.9 was changed from 'offer' to 'consider' because it contradicted the new recommendations on margins after surgery for DCIS.
- In recommendation 1.10.17, 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 1.10.19, the term 'axilla and supraclavicular fossa' has been changed to 'regional lymph nodes'.
- In recommendation 1.10.20, the term 'ALND' has been changed to 'axillary clearance'.
- In recommendation 1.12.17, 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.

Minor changes since publication

March 2024: Evidence review N was amended to add a missing study. The rationales for DCIS in section 1.3 were updated but there were no changes to the recommendations.

May 2022: We added a link to NICE's guideline on medicines associated with dependence or withdrawal symptoms in the section on menopausal symptoms.

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