NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Scope for guideline update (starting 2025)

Familial breast cancer: classification, care and managing breast cancer and related risks in people with a family history of breast cancer

NICE is updating its guideline on Familial breast cancer: classification, care and managing breast cancer and related risks in people with a family history of breast cancer (CG164).

The update will be developed using the methods and processes in developing NICE guidelines: the manual.

Who the guideline update covers

The update will expand the guideline population to cover people who do not have a family history of breast cancer, but are suspected of having an inherited predisposition to developing breast cancer for other reasons. At publication of the update the guideline will be renamed to reflect this wider population.

For the purposes of this document, the following definitions are used:

- ancestry: this refers to ancestry with a high prevalence of pathogenic variants associated with an increased risk of breast cancer
- clinical or pathological features associated with heritable breast cancer: this refers to clinical features such as onset of breast cancer before 40 years old, bilateral breast cancer and male breast cancer, and pathological features such as having triple negative breast cancer
- family history: this refers to a family history of breast or ovarian cancer or a related cancer or where a breast cancer susceptibility gene has already been identified in another family member.

- personal history of breast cancer: this refers to the person having or having had high-grade ductal carcinoma in situ (DCIS), invasive breast cancer or both, but does not include low or intermediate grade DCIS or B3 lesions of indeterminate nature.

Overall guideline population

- Women, trans men and non-binary people born with female reproductive organs, and trans women and non-binary people born with male reproductive organs who have been on female gender affirming hormone therapy for 5 years or more, aged 18 years and older with a personal history of breast cancer who:
  - may have an inherited predisposition to developing breast cancer because of family history, ancestry, or because they have clinical or pathological features associated with heritable breast cancer
  - have a confirmed pathogenic variant that predisposes them to developing breast cancer.
- The same population as above with no personal history of breast cancer who may have an inherited predisposition to developing breast cancer because of a family history or ancestry, or who have a confirmed pathogenic variant that predisposes them to developing breast cancer.

Populations for specific areas of the guideline

1 For assessment of carrier probability only, in addition to the populations listed above:
   - women, trans men and non-binary people born with female reproductive organs, and trans women and non-binary people born with male reproductive organs who have been on female gender affirming hormone therapy for 5 years or more, aged 18 years and older with a personal history of breast cancer, regardless of any suspected inherited predisposition to developing breast cancer.

2 For assessment of carrier probability testing and germline genetic testing, in addition to the overall guideline population:

- men, trans women and non-binary people born with male reproductive organs who have been on female gender affirming hormone therapy for less than 5 years, aged 18 and over, with a personal history of breast cancer regardless of any suspected inherited predisposition to developing breast cancer
- the same population as above, with no personal history of breast cancer, but who may be at increased risk of developing breast cancer because of a family history or ancestry.

Note: the 5-year threshold was chosen based on the UK recommendations for the management of transgender and gender-diverse patients with inherited cancer risks (see Table 2, section 4 on breast tissue management).

Equality considerations

A new equality and health inequalities assessment impact has been completed.

Settings

This guideline will cover all health, mental health and social care settings in which NHS care or social care is received or commissioned.

Activities, services or aspects of care covered by the guideline update

We will consider making recommendations or updating existing recommendations in the following sections of the current guideline (the headings of the sections may change as part of the update and new ones may be introduced):

Clinical significance of a family history of breast cancer

- Family history and carrier probability.

Genetic testing

- Carrier probability at which genetic testing should be offered

- Mutation tests
- Genetic testing for BRCA1, BRCA2 and TP53 mutations within 4 weeks of diagnosis of breast cancer.

Surveillance and strategies for early detection of breast cancer

- Surveillance for women with no personal history of breast cancer
- Surveillance for women with a personal and family history of breast cancer
- Recommendations for all women having surveillance.

Risk reduction and treatment strategies

- Risk-reducing breast surgery for women with or without a personal history of breast cancer
- Hormonal contraceptives.

This guideline update will not cover

We will not be reviewing the evidence on the following:

Clinical significance of a family history of breast cancer

- Family history-taking and initial assessment in primary care
- Family history-taking in secondary care
- Family history-taking in a specialist genetic clinic
- Communicating cancer risk and carrier probability.

Information and support

Care of people in primary care

- Care and management of people in primary care
- Referral from primary care
- Patient education and information
- Support for primary care.

Care of people in secondary care and specialist genetic clinics

- Care and management approach in secondary care
- Referral to a specialist genetic clinic
- Care of people in a specialist genetic clinic
- Genetic counselling for people with no personal history of breast cancer.

Risk reduction and treatment strategies

- Risk factors
- Menstrual and reproductive factors
- Hormone replacement therapy
- Breastfeeding
- Alcohol consumption
- Smoking
- Weight and physical activity
- Chemoprevention for women with no personal history of breast cancer
- Risk-reducing oophorectomy.

We plan to retain the recommendations in these areas, although they may be revised to update language, reflect current policy or practice, and to ensure consistency with new content.

Draft review questions

We have identified the following draft review questions. These may change during guideline development, but the areas covered will remain as listed in the final scope.

The areas covered and draft questions will be used to develop more detailed review questions.

Assessing carrier probability

1. What are the optimal methods of assessing the probability of having a pathogenic variant in breast cancer predisposition genes in people who have either:

    - a personal history of breast cancer or
    - no personal history of breast cancer but a family history of breast, ovarian or a related cancer, or ancestry with a high prevalence of pathogenic variants associated with an increased risk of breast cancer?

Determining the carrier probability at which germline genetic testing should be offered

2. At what carrier probability should people with a personal history of breast cancer be offered germline genetic testing for breast cancer predisposition genes?

3. At what carrier probability should people without a personal history of breast cancer be offered germline genetic testing for breast cancer predisposition genes?

Assessing the risk of developing breast cancer

4. Which risk prediction tools can most accurately predict the risk of developing future new primary breast cancer in either:

    - people with a personal history of breast cancer who may have an inherited predisposition to developing breast cancer because of family history, ancestry, or because they have clinical or pathological features associated with heritable breast cancer or have a confirmed pathogenic variant that predisposes them to developing breast cancer or
    - people with no personal history of breast cancer who have a family history of breast, ovarian or a related cancer, ancestry with a high prevalence of pathogenic variants associated with breast cancer or a confirmed pathogenic variant that predisposes them to developing breast cancer?

Risk-reducing surgery

5. How effective and cost effective is risk-reducing mastectomy in women, trans-men and nonbinary people born with female reproductive organs who are at increased risk of heritable breast cancer (considering risk thresholds, previous cancer history, specific pathogenic variants, and age)?

Economic aspects

We will take economic aspects into account when making recommendations. For each review question (or key areas in the scope), we will review the economic evidence and, where appropriate, carry out economic modelling and analyses, using an NHS and personal social services perspective.

NICE guidance and quality standards that may be affected by this guideline update

- Ovarian cancer: identifying and managing familial and genetic risk (2024). NICE guideline NG241
- Early and locally advanced breast cancer: diagnosis and management (2018). NICE guideline NG101
- Menopause: identification and management (2015). NICE guideline NG23
- Ovarian cancer (2025). NICE quality standard 18
- Breast cancer (2011). NICE quality standard 12

Further information

The guideline update is expected to be published in April 2027.

To follow the progress of the update, see the guideline in development page.

Our website has information about how NICE guidelines are developed.

NICE guidelines cover health and care in England. Decisions on how they apply in other UK countries are made by ministers in the Welsh Government, Scottish Government and Northern Ireland Executive.