

# **NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

**Equality and health inequalities assessment (EHIA)**

## STAGE 2. Informing the scope

NG101 Early and locally advanced breast cancer

Date of completion: 12/02/2024

Focus of guideline or update:

- Neoadjuvant chemotherapy regimens
- Gonadal function suppression (formerly Ovarian function suppression)

2.1 What approaches have been used to identify potential equality and health inequalities issues during the check for an update or during development of the draft scope?

This document has been compiled using information taken from the [surveillance stage EHIA](#) that accompanied the [2023 surveillance review](#). Further searches were conducted to identify equality issues specific to this topic and discussions were held with committee members during scoping. Equality issues that were identified during the scoping and development of the [2018 update](#) and the [health inequalities briefing](#) that accompanies this guideline have also been considered.

2.2 What potential equality and health inequalities issues have been identified during the check for an update or during development of the draft scope?

In this document when we refer to ovarian function suppression, it is in relation to its use as a treatment for breast cancer not as a means of preserving fertility during chemotherapy. The latter use of ovarian function suppression is not covered by the scope of this update.

Although the term gonadal function suppression is an umbrella term that encompasses ovarian function suppression as well as treatments to suppress testicular function, in this document when we refer to gonadal function suppression, we mean a treatment targeted at people with male reproductive organs. We have retained the term 'ovarian function suppression' to refer to treatments targeted at people with female reproductive organs.

### 1) Protected characteristics

#### a. Age

The incidence of breast cancer increases with age from less than 100 per 100,000 people aged 49 and younger to more than 150 per 100,000 people aged 65 and older ([NHS Digital](#)) and with an aging population more older people may be now diagnosed with early or locally advanced invasive breast cancer. Neoadjuvant

chemotherapy (given prior to surgery) is a potential treatment option but older people may be less likely to be offered or take up these treatments.

There is evidence to suggest that older people should be treated based on tumour biology as for younger patients ([Ring et al. 2011](#)). However data shows that the use of neoadjuvant pertuzumab, a treatment given alongside neoadjuvant chemotherapy for HER2 positive breast cancer, decreases as women get older ([Gannon et al. 2023](#)) and that oncologists are less likely to prescribe chemotherapy for high risk breast cancer in older women ([Ring 2010](#)). The [health inequalities briefing](#) also shows that chemotherapy use declines with age ([NHS Digital, 2022](#)). This is particularly the case in women aged 80 and over and is in line with the 2018 national breast cancer audit ([Ageism in breast cancer 2019](#)) which found that chemotherapy use declines with age regardless of tumour characteristics. However, [Smith et al. \(2016\)](#) reported that 14% of older women (70 years and older) would be prepared to consider neoadjuvant chemotherapy to shrink their tumour to facilitate breast conserving surgery.

Although some older people may be suitable for neoadjuvant treatment others may not be based on their level of frailty and number/ types of co-morbidities they have. For these latter groups of people there could be an increased risk of treatment related adverse events leading to poor outcomes ([National Audit of Breast Cancer in Older Patients, Annual Report 2022](#)). However, decisions about whether to offer a particular type of treatment should be based on the patient's fitness and ability to benefit from the treatment rather than only their chronological age ([All Party Parliamentary Group on Breast Cancer 2013](#)).

Older people with cognitive impairment or dementia may need support with decision making. Others may need information provided in a suitably accessible manner if they have hearing impairment or visual impairment). Older people may also face a range of barriers to taking up an offer of neoadjuvant chemotherapy. These can include increasing frailty, reduced physical ability, comorbidities and existing or new disabilities that make it harder for them to travel to appointments (see also the section on Disability). They may be resident in a care home or rely on family or carers to help them access chemotherapy and some older people have little access to such social and practical support. This may be particularly problematic for treatment with neoadjuvant chemotherapy, which is given in cycles every few weeks. In addition, people who have help with their activities of daily living (such as dressing themselves or preparing food) may require additional support to help them cope with the effects of the chemotherapy.

In contrast, other older people may have caring responsibilities that prevent them from accessing chemotherapy.

Specialist units for older age oncology may support a higher uptake of chemotherapy by older people, but access is inequitable as such services are not available in all areas.

Although breast cancer incidence increases with age, some types of breast cancer such as triple negative breast cancer (TNBC) are more likely to affect younger women of childbearing age ([Cancer Research UK 2023](#)). Younger people with invasive breast cancer are likely to be offered surgery and therefore be considered for the neoadjuvant chemotherapies being reviewed in this update. They are also likely to be considered for ovarian function suppression if they have ER positive breast cancer and are pre- or perimenopausal.

Younger women with breast cancer may face a range of barriers to accessing neoadjuvant chemotherapy and ovarian function suppression linked to motherhood and reproduction (see also the section Pregnancy and maternity). Young childless women might not be given adequate information and choices about fertility issues before and after breast cancer treatment ([Corney and Swinglehurst 2014](#)), which may adversely affect their decisions about accepting treatment. In particular, they may be very concerned about accepting an offer of ovarian function suppression, which induces an early permanent or transient menopause. Other women who already have children may also be very concerned about the impact of treatments on their fertility or they may have different priorities due to existing childcare needs. The impact of these therapies on fertility may not be communicated clearly with patients prior to treatment and can be a major cause of concern to them ([Lee et al. 2011](#)). In addition, there may be a lack of timely access to services for fertility preservation and this could delay the start of neoadjuvant treatment. Younger women may also be very concerned about the negative effects of menopausal symptoms on their lives, including effects on energy levels, and in the longer term, effects on their heart and bone health. They may require additional support to help them cope with the effects of the chemotherapy and this could impact on their ability to care for themselves and others.

Treatment with neoadjuvant chemotherapy and/or ovarian function suppression may involve multiple appointments and younger people may have difficulties with attending these if they have caring commitments (for example childcare or care for older relatives). They may also have difficulties attending appointments if there is no flexibility about the time of day (for example if they have to pick up children from school or if they have problems getting time off work (see also issues listed under Socioeconomic deprivation)).

While some people may have surgery to remove their ovaries, or ablation of the ovaries through radiation treatment, an alternative option is drug treatment to suppress ovarian function, which is potentially reversible. Drug treatments can be delivered monthly or every 3 months, depending on the prescribed treatment option.

Depending on the treatment and local provision the distance people have to travel can also vary with some people being able to receive drug treatments for ovarian function suppression at their GP surgery while others have to attend a hospital.. A lack of choice about the type of ovarian function suppression available and where it is delivered may limit the ability of some women to benefit from this treatment.

Finally, younger and older people with breast cancer are often not included in the eligibility criteria for clinical trials and so there is likely to be much less good quality evidence about effective treatment options for these groups of people.

#### b. Disability

The [Equality Act \(2010\)](#) defines a disabled person as a person with a physical or mental impairment that ‘has a substantial and long-term adverse effect’ on the person’s ‘ability to carry out normal day-to-day activities.’ For this section we will include the groups of people covered by the act although we recognise that this includes a wide range of people, some of whom may not consider themselves to be disabled but rather differently abled (such as some neurodivergent people).

Research relating to disabled women suggests that they are less likely to undergo breast-conserving surgery and are less likely to receive neoadjuvant chemotherapy and radiotherapy than their peers without disabilities ([Heslop et al. 2022](#)). There are a range of barriers to accessing treatment that disabled people with breast cancer may face that could account for this result.

One key barrier is related to the communication of information and informed decision making. Information needs to be provided in an accessible manner to everyone to facilitate decision making. Some disabled people have additional information needs and require information to be provided in a manner that addresses these needs to be fully accessible. However, the type of accessible information needs to be tailored to individual requirements as it will vary with the type of disability, while other disabled people may not have additional information needs. For example, people with learning disabilities may require easy read information leaflets or verbal information about neoadjuvant chemotherapy and gonadal/ ovarian function suppression. In contrast, people with sensory disabilities (for example, people with visual impairment) may require information presented in Braille and verbally. Some disabled people (for example, people with learning disabilities, dementia or who have more severe forms of autism) may require the support of a carer or advocate to help them to understand what is happening to them and to ensure that the consent that they give is informed, whilst others won’t have this need (for example, people who use a wheelchair may not need additional support in this area). As well as having information provided to them in a way they can understand and process, neurodivergent people may also need support to adapt to changes in their routine and with physical examinations.

Some disabled people (such as those with dementia, learning disabilities or physical disabilities that affect mobility) may face difficulties in travelling to a treatment centre

to receive neoadjuvant therapy or gonadal/ ovarian function suppression due to its geographical location (for example, if the centre is far away and there is limited or no accessible transport to it). This problem may be compounded if they need to attend multiple and regular appointments (for example, neoadjuvant therapy is delivered in cycles of treatment). Disabled people may also be more likely to be living in poverty (see also the section on Socioeconomic status and deprivation). The lack of availability of family, carers or support workers to accompany and support them in their appointments at the treatment centre could also be a barrier to access for some disabled people. Additional preparation and support may also be needed to help some disabled people, such as those with learning disabilities or neurodivergent people, get used to the treatment environment before they receive therapy.

People with mental health conditions (for example, anxiety or depression) may also need additional support in completing their treatment plans because they may find it difficult to engage in breast cancer services due to their psychological symptoms. The effects of gonadal/ ovarian function suppression on the balance of hormones could also lead to a worsening of their symptoms. In addition, concerns about long term fertility may exacerbate people's mental health conditions.

c. Gender reassignment

Trans people or people who are non-binary may face barriers in accessing gender-affirming healthcare. Breast cancer services are mostly used by women and a trans man who attends these services is likely to be surrounded by women for example, in clinic waiting rooms. This could cause a lot of anxiety as they may feel that they are being forced back into or given an unwanted reminder of a gender they believed they had left behind. In addition, the limited availability of healthcare providers experienced in trans healthcare and insufficient training in trans-specific needs can result in delayed diagnosis and inadequate treatment.

People who are undergoing gender transition may have concerns about the impact of neoadjuvant treatments and gonadal/ ovarian function suppression on their plans for transition and concerns about the impact of any gender-affirming treatments on any treatments for cancer. However, trans people are poorly represented in clinical trials and as a result there is uncertainty around effective treatment options for them. The effects and suitability of a person for neoadjuvant chemotherapy or gonadal/ ovarian function suppression will differ between trans men and trans women and will be affected by the treatment they have had or are having for gender reassignment, particularly if this involves hormone treatment. It may be necessary to liaise with the clinicians managing the gender transition to decide on and co-ordinate suitable treatment.

d. Marriage and civil partnership

No potential issues identified.

e. Pregnancy and maternity

Pregnant women may be excluded from trials of neoadjuvant drugs leading to increased uncertainty about when during pregnancy they (and trans men and non-binary people who are pregnant) are able to safely take these drugs. People taking these drugs may not be able to breastfeed for the duration of treatment. They may also have concerns about the effects of the neoadjuvant drugs and ovarian function suppression on fertility and the ability to have more children in the future (see the section on Age above for more information about this topic).

f. Race

The [health inequalities briefing](#) shows recent NHS data on the use of overall chemotherapy (data is not specific for neoadjuvant chemotherapy) which is slightly higher in people from non-white family backgrounds ([NHS Digital 2022](#)) compared to people from White family backgrounds. However, there is evidence to suggest that some women from minority ethnic groups, and in particular Black women, may be less likely to continue taking their hormone therapy than White British women ([McGuinness et al. 2022](#)). Similar considerations may apply to people taking gonadal/ovarian function suppression therapy. In addition, treatments that impact fertility may not be acceptable in some cultures.

The differences in uptake of chemotherapy and hormone therapy based on race were also found in a study by [Jack et al. 2009](#) using data from South East England. They suggested this might be linked to differences in the type of breast cancer that Black Caribbean and Black African women were likely to have and the stage at which their cancer was identified. There is an increased rate of triple negative breast cancer in people from ethnic minority backgrounds, with evidence to suggest that Black and South Asian women are more likely to have triple negative breast cancer compared to White women ([Jack et al. 2013](#)). Consistent with this, there is evidence to suggest that women with breast cancer aged 30 to 46 years old from Pakistani, Black Caribbean and Black African family backgrounds had less favourable tumour characteristics (stage, grade, ER and HER2 status) ([Gathani et al. 2021](#)). They were also more likely to score in the most deprived quintile of the index of multiple deprivation compared to White and Indian women. Evidence was similar for older women (53 to 70 years) with more marked differences for women from Black Caribbean and Black African family backgrounds. These characteristics have an effect on the type of neoadjuvant chemotherapy regimen that is suitable.

Ethnic minority groups in the UK may face disparities in breast cancer care. Factors such as language barriers, cultural beliefs and limited awareness of breast cancer care can influence access to timely diagnosis and treatment. Ethnic minorities may also face biases, stereotypes, and discrimination within the healthcare system.

Ethnic minorities who have limited English proficiency may face challenges in navigating the healthcare system, understanding medical instructions, and making informed decisions about treatment options.

g. Religion or belief

Religious or cultural beliefs can influence treatment decisions, including the acceptance or rejection of treatments for breast cancer. In particular, treatments that impact fertility may not be acceptable in some religions or belief systems. Some people may rely on alternative or complementary therapies which could lead to delays or avoidance of certain treatments. In addition, some people may use specific healthcare practices alongside chemotherapy, such as seeking care from traditional healers, undertaking specific rituals, or employing dietary restrictions that could impact outcomes.

h. Sex

Breast cancer primarily affects women, trans men and non-binary people registered female at birth; however, men, trans women and non-binary people registered male at birth can also have breast cancer. Men, trans women and non-binary people registered male at birth with breast cancer may face additional challenges in terms of delayed diagnosis and gender biases and a lack of knowledge about suitable treatments for them. There is some evidence to suggest that male breast cancer may respond differently to systemic therapies compared to female breast cancer ([Patten et al. 2013](#)), however men, trans women and non-binary people registered male at birth are also often underrepresented in or excluded from breast cancer clinical trials and are underrepresented in breast cancer guidelines as a result. (See section 2.3 for an example of an issue the committee have identified and will endeavour to address as part of this update.)

The [health inequalities briefing](#) notes that there is a lack of gender-specific information on breast cancer for men ([Breast Cancer Care, 2011](#)). For example, men would like information about sex-specific chemotherapy side effects.

i. Sexual orientation

No potential issues identified

2) Socioeconomic deprivation

There is evidence to suggest that lower proportions of women had chemotherapy in the most deprived areas of Scotland compared to the least deprived areas regardless of oestrogen receptor (ER) status ([Mesa-Eguiagaray et al. 2022](#)). In contrast proportions of women who received hormone therapy were very similar across deprivation quintiles ([Mesa-Eguiagaray et al. 2022](#)). This may also be the case for women receiving ovarian function suppression therapy.

People from lower socioeconomic backgrounds or who are experiencing poverty may face barriers to accessing neoadjuvant chemotherapy and gonadal /ovarian function



suppression. This could be due to the limited availability of healthcare facilities and long waiting times for treatment in their local areas. Problems with the availability and cost of transport could also adversely affect their ability to attend appointments and alter their choice of treatment. Moreover, some people from lower socioeconomic backgrounds or who are living in poverty may find it difficult to attend multiple appointments for these treatments due to their employment status. These could include people on zero-hour contracts or people who will not be paid if they are absent from work due to medical appointments or sickness, for example. They may also lack suitable support and adjustments from their employers when they return to work, and this could limit their choice of treatment to avoid chemotherapy-related side effects. While these issues may not be confined to people from lower socioeconomic groups and may also be experienced for example, by people who are self-employed, those who are on low incomes may be disproportionately affected.

### 3) Geographical area variation

The NeST (neoadjuvant systemic therapy in breast cancer) study concluded that there is variation in use of and decision-making around neoadjuvant chemotherapy across the UK, with surgical downstaging more apparent in the breast than the axilla, and variation according to disease subtype ([Fatayer et al. 2022](#)). Data shows that there are differences in the use of neoadjuvant pertuzumab for HER2 positive breast cancer, by government office region with lower percentages in the North East, Yorkshire & Humber, South East, East Midlands, and London (from 24.6% to 27.4%) and higher percentages in the South West, East England, West Midlands, and the North West (from 30.4% to 35.1%) ([Gannon et al. 2023](#)). In addition, an inquiry into geographical inequalities and breast cancer found evidence about geographical variation in the use of hormonal therapies such as tamoxifen and geographical variation on whether people were told about the impact of treatment on their fertility ([All-Party Parliamentary Group on Breast Cancer 2018](#)).

In certain regions or rural areas specialist breast cancer care facilities may be limited and people may have to travel long distances to access treatment. For example, specialist units for older age oncology are available in some areas of the country but not others. In addition, there is variation in where ovarian function suppression treatment is provided (at a GP surgery or a hospital). This would be expected to have a particular impact on people who have difficulties in traveling longer distances due to caring responsibilities, a lack of transport, a shortage of money, disabilities or older age. There is evidence to suggest that the 'extra travel time to treatment centres, costs (for example, on parking and fuel) and inconvenience for rural patients and carers can compound what is already a stressful situation ([Breast Cancer Care 2011](#)).' It may also limit their treatment options.

### 4) Inclusion health and vulnerable groups

'Inclusion health is an umbrella term used to describe people who are socially excluded, who typically experience multiple overlapping risk factors for poor health, such as poverty, violence and complex trauma' ([NHS England](#)). The following groups in this section were identified in relation to health inequalities and neoadjuvant chemotherapy or gonadal/ovarian function suppression.

Health literacy is the ability to obtain, read, understand, and use healthcare information in order to make appropriate health decisions and follow instructions for treatment. People with low levels of health literacy and awareness about breast cancer symptoms may face barriers to being diagnosed and with being able to manage their breast cancer. For example, the lack of access to health education, language barriers, and limited knowledge about breast cancer symptoms, available resources and support services can result in delayed diagnosis and poorer outcomes. This issue may disproportionately affect individuals from lower socioeconomic backgrounds or deprived communities, although [people with higher socioeconomic status](#) may also experience this.

People experiencing homelessness can face many challenges to accessing breast cancer surgery and treatment. They may experience delays with diagnosis and treatment, have problems travelling to appointments, and limited access to support after treatment. This can impact their choice of treatment, recovery, functional outcomes, and overall well-being. They may also have low levels of health literacy and additional complex health needs.

Newly arrived migrants may face difficulties with accessing healthcare and may, in some cases, be afraid to use health services because they think they are ineligible or because they think it will alert the authorities and they will be arrested and deported. Migrants who do not have access to free NHS care may have problems in being able to afford breast cancer treatment in general, which could be expensive as reported charges levied range from £40 up to £80,000 ([Doctors of the World 2017](#)). The additional barriers they face can include limited knowledge about the healthcare system, limited availability of culturally and linguistically appropriate healthcare services/resources which can lead to difficulties in navigating the healthcare system in a new country. Moreover, limited knowledge about breast cancer, including screening practices, symptoms, and available treatments, can contribute to delays in diagnosis and treatment for newly arrived migrants. Differences in healthcare systems and practices between the home country and the host country may also contribute to delays in seeking appropriate medical care. Newly arrived migrants may not have a permanent address and therefore they may face similar challenges as people experiencing homelessness (see above). They may also have financial difficulties and be living in poverty (see the section on socioeconomic status and deprivation above for additional challenges that they may face as a result).

People who are in prison may face difficulties in accessing breast cancer treatment. They may experience delays with diagnosis and treatment, have problems attending multiple rounds of neoadjuvant therapy or gonadal/ovarian function suppression due to their incarceration and prison staff availability. This can impact their outcomes and may influence their choice of treatment. They may also have additional complex health needs such as mental health issues and have low levels of health literacy.

2.3 How can the identified equality and health inequalities issues be further explored and considered at this stage of the development process?

During scoping the committee identified that men are underrepresented in breast cancer guidelines. While the existing guideline makes recommendations on ovarian function suppression being given in addition to endocrine therapy for women, there are no recommendations on gonadal function suppression in men. This is despite tamoxifen being recommended as an initial adjuvant endocrine therapy in both pre-menopausal women and in men. The committee agreed that this update of the guideline should therefore include gonadal function suppression for people with male reproductive organs, so that if good quality evidence is available, appropriate advice can be provided for both men and women.

The guideline update aims to give special considerations for the subpopulations identified in box 2.2 by taking these groups into consideration when developing the review protocol and making recommendations. During the protocol development stage, the committee will consider whether evidence specific to the subpopulations should be sought and whether data should be analysed separately.

Specific recommendations could include:

- Referring to NICE's guidelines on making decisions about care (for example, [Shared decision making](#) [NG197] and [Patient experience in adult NHS services: improving the experience of care for people using adult NHS services](#) [CG 138])
- Referring to the [Accessible Information Standard](#) which aims to make sure that people who have a disability, impairment or sensory loss get information that they can access and understand, and any communication support that they need from health and care services.
- Different formats and delivery of information (for example, leaflets and written information which can include easy read format and braille; videos and graphics) and providing information in different languages and/ or using translators to facilitate understanding of spoken information or instructions.
- Gender neutral information and information for people of different gender identities.

- Ensuring culturally appropriate care, such as acknowledging why treatment by a healthcare professional of a specific gender is required and accommodating this request if there is staff availability.
- Recommendations aimed at improving the quality of breast cancer care.
- Research recommendations to try to address gaps in the evidence base for people with equalities issues.

2.4 Do you have representation from stakeholder groups that can help to explore equality and health inequalities issues during the consultation process including groups who are known to be affected by these issues? If not, what plans are in place to address gaps in the stakeholder list?

The original list of stakeholders did not include many patient groups. Prior to consultation we identified relevant groups with the help of the Patient Involvement Programme (PIP) and invited them to become stakeholders.

2.5 How will the views and experiences of those affected by equality and health inequalities issues be meaningfully included in the guideline development process going forward?

Lay members who have lived experience of breast cancer and neoadjuvant chemotherapy or ovarian function suppression treatment have been recruited as part of the committee. They will be involved in committee discussions about the evidence and decisions about recommendations. They will also be asked to discuss how the suggested recommendations fit with their personal experiences.

Groups representing people who experience health inequalities will be able to comment on the guideline during consultation if they are registered as stakeholders. In addition, we will invite groups we identify with the committee and through other intelligence sources to register as stakeholders if they have not already done so.

2.6 If applicable, what questions will you ask at the draft scope stakeholder consultation about the guideline/update and potential impact on equality and health inequalities?

No questions that relate to health inequalities will be asked in the scope consultation.

2.7 Has it been proposed to exclude any population groups from the scope? If yes, how do these exclusions relate to any equality and health inequalities issues identified?
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Some population groups are excluded from the scope of this update as the treatments under review are not appropriate for them. None of the groups that have been identified in this document are excluded from the scope of this work. However, certain treatments may not be appropriate for certain groups of people listed in this document (for example, ovarian function suppression would not be suitable for pregnant women).
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**Completed by developer:** Yolanda Martinez, Karen Peploe and Marie Harrisingh

**Date:** 12/02/2024

**Approved by committee chair:** Adam Firth

**Date:** 25/03/2024

**Approved by NICE quality assurance lead:** Kate Kelley

**Date:** 25/03/2024

## STAGE 3. Finalising the scope

NG101 Early and locally advanced breast cancer

Date of completion: 14/05/2024

Focus of guideline or update:

- Neoadjuvant chemotherapy regimens
- Gonadal function suppression (formerly Ovarian function suppression)

3.1 How inclusive was the consultation process in terms of response from stakeholders who may experience inequalities related to the topic (identified in 2.2)?

In total 264 potential stakeholder organisations were identified for this guidance and were invited to participate in the consultation. Comments were received from 3 organisations. The responding organisations were a major voluntary sector organisation (Breast Cancer Now), the NHSE Clinical Programmes Team and the NHSE Test Evaluation Team Genomics Unit. Two of the stakeholders referred to the proposed review of Gonadal function suppression in men and were supportive of this work. Additional contact with stakeholders post consultation did not lead to any new equality and health inequalities issues being identified.

3.2 Have any additional equality and health inequalities issues been identified during consultation? If so, what were they and what potential solutions/changes were suggested by stakeholders to address them?

1) Protected characteristics

No further issues were identified.

2) Socioeconomic deprivation

No further issues were identified.

3) Geographical area variation

No further issues were identified.

4) Inclusion health and vulnerable groups

No further issues were identified.

3.3 Have any changes been made to the scope as a result of the consultation and equality and health inequalities issues identified in 2.2 and 3.2? Were any other changes made to the scope that may impact on equality and health inequalities?

No changes were made to the scope as a result of the comments received at consultation because none of the comments raised new equality and health inequalities considerations. Other changes made to the scope were few and were minor points of clarification that do not impact on equalities issues.

**Completed by developer:** Yolanda Martinez and Marie Harrisingh

**Date:** 14/05/2024

**Approved by committee chair:** Adam Firth

**Date:** 23/05/2024

**Approved by NICE quality assurance lead:** Kate Kelley

**Date:** 09/07/2024

## STAGE 4. Development of guideline or topic area for update

NG101 Early and locally advanced breast cancer

Date of completion: 10/12/2024

Focus of guideline or update:

- Neoadjuvant chemotherapy regimens
- Gonadal function suppression (formerly Ovarian function suppression)

4.1 From the evidence syntheses and the committee's considerations thereof, what were the main equality and health inequalities issues identified? Were any **further** potential issues identified (in addition to those identified during the scoping process) or any gaps in the evidence for any particular group?

1) Protected characteristics outlined in the Equality Act 2010

a. Age

There was limited evidence about the effectiveness of neoadjuvant chemotherapy for older people who have triple negative breast cancer (TNBC) or who have human epidermal growth factor receptor 2 (HER2) positive invasive breast cancer as the participants of the included studies had median ages of around 50 years . The committee acknowledged that older people (people aged 65 years and over) are also at risk of having TNBC or HER2-positive breast cancer but are often excluded from trials or only form a small proportion of the population due to concerns about potential frailty and comorbidities.

b. Disability

No further issues were identified.

c. Gender reassignment

No further issues were identified.

d. Marriage and civil partnership

No further issues were identified.

e. Pregnancy and maternity

There was no evidence for the effectiveness of neoadjuvant chemotherapy for people who are pregnant and have triple negative breast cancer or have HER2-positive invasive breast cancer. The committee acknowledged that pregnant people are also at risk of having TNBC or HER2-positive breast cancer but are often excluded from trials due to concerns about the risk of causing problems during development of the baby.

f. Race

No further issues were identified.



g. Religion or belief

No further issues were identified.

h. Sex

There was no evidence for the effectiveness of neoadjuvant chemotherapy for people with male reproductive organs who have triple negative breast cancer or who have HER2-positive invasive breast cancer. The committee acknowledged that people with male reproductive organs are also at risk of having TNBC or HER2-positive breast cancer but are often excluded from trials or only form a small proportion of the population due to limited numbers of people with male reproductive organs who have breast cancer.

There was limited evidence for the effectiveness of testicular function suppression (TFS) for people with male reproductive organs who have ER-positive breast cancer. The committee acknowledged that TFS will affect fertility and this should be discussed with the person who is about to take this treatment.

i. Sexual orientation

No further issues were identified.

2) Socioeconomic deprivation

No further issues were identified.

3) Geographical area variation

No further issues were identified.

4) Inclusion health and vulnerable groups

No further issues were identified.

4.2 How have the committee's considerations of equality and health inequalities issues identified in 2.2, 3.2 and 4.1 been reflected in the guideline or update and any draft recommendations?

The committee's discussions about equality and health inequalities issues are included in the following evidence reviews under the section on other factors the committee took into account in the committee's discussion of the evidence:

- evidence review O: platinum based neoadjuvant chemotherapy
- evidence review P: neoadjuvant chemotherapy for people with HER2 positive breast cancer
- evidence review Q: ovarian function suppression
- evidence review R: testicular function suppression

To facilitate the decision-making process and ensure that patients are able to fully participate the committee added cross references to relevant sections of some core NICE guidelines in the overarching section of the guideline that covers systemic anti-cancer therapy planning. These were the sections 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](#). This section will apply to recommendations from all of the reviews in this update listed above.

In addition, in review O about platinum based neoadjuvant chemotherapy for people with triple negative breast cancer, the committee recommended that the person's circumstances, needs and preferences should form part of the decision-making process to ensure that the realities of people's lives are taken into account and to help identify and minimise the impact of health inequalities, where possible.

Review R on testicular function suppression was carried out specifically to address a gap in the guideline in relation to endocrine treatment for people with male reproductive organs who have ER-positive invasive breast cancer and resulting health inequality that this caused. The committee made several specific recommendations for this population.

#### 4.3 Could any draft recommendations potentially increase inequalities?

No, this is not expected to be the case.

#### 4.4 How has the committee's considerations of equality and health inequalities issues identified in 2.2, 3.2 and 4.1 been reflected in the development of any research recommendations?

A research recommendation was made to address the gaps in the evidence for groups of people (people 65 years and older, people who are pregnant, people with male reproductive organs) about the effectiveness clinical and cost effectiveness of adding a platinum to a neoadjuvant chemotherapy regimen in people with invasive breast cancer that is triple negative and/or with a germline BRCA mutation. The committee considered the lack of evidence to be due to poor representation of these groups in clinical trials so considered real world evidence as an option to address this gap in the evidence.

Two research recommendations were made to try to address the lack of evidence about the effectiveness of testicular function suppression and around the types and severity of side effects experienced by people with ER-positive invasive or metastatic breast cancer, who have male reproductive organs.

4.5 Based on the equality and health inequalities issues identified in 2.2, 3.2 and 4.1, do you have representation from relevant stakeholder groups for the guideline or update consultation process, including groups who are known to be affected by these issues? If not, what plans are in place to ensure relevant stakeholders are represented and included?

Due to the large number of potential groups involved we plan to try to engage with people from relevant groups during consultation. We have a number of patient organisations registered for consultation that we will ask for feedback on our recommendations including Breast Cancer UK, Breast Cancer Now, Can-Survive UK and Flat Friends UK. We will also approach any other groups that are suggested by the committee to ask if they would like to register as stakeholders.

4.6 What questions will you ask at the stakeholder consultation about the impact of the guideline or update on equality and health inequalities?

No specific questions will be asked about equality and health inequalities, but we will ensure that any comments from relevant stakeholders are considered and discussed with the committee, and changes will be made where necessary.

**Completed by developer:** Yolanda Martinez, Sarah Boyce and Marie Harrisingh,

**Date:** 13/12/2024

**Approved by committee chair:** Adam Firth

**Date:** 30/01/25

**Approved by NICE quality assurance lead:** Kate Kelley

**Date:** 29/01/25

## STAGE 5. Revisions and final guideline or update

NG101 Early and locally advanced breast cancer

Date of completion: 17/03/2025

Focus of guideline or update:

- Neoadjuvant chemotherapy regimens
- Gonadal function suppression (formerly Ovarian function suppression)

5.1 How inclusive was the consultation process on the draft guideline in terms of response from groups (identified in box 2.2, 3.2 and 4.1) who may experience inequalities related to the topic?

The NICE Public Involvement Programme helped to identify relevant stakeholders. The final stakeholder list was reviewed by Public Involvement Programme colleagues and the committee to identify any potential gaps.

Registered stakeholders were invited to respond to the draft guideline during consultation.

Stakeholders were from a variety of organisations including:

- national patient, carer and voluntary organisations
- charities
- national organisations representing public health, healthcare and other professionals who provide the activities and services related to the updated guidance in England
- local authorities and representative bodies of local government
- providers of public health, health and social care in England and Wales, commercial industries which are relevant to the updated guidance
- the Department of Health and other relevant Government departments and agencies
- research organisations and academic institutions across the UK.

Eight of these stakeholder groups responded during consultation. These were a mix of patient organisations and charities, a government agency and national organisations representing healthcare professionals. All comments were addressed and were responded to individually. Comments and responses will be published on our website.

5.2 Have any **further** equality and health inequalities issues beyond those identified at scoping and during development been raised during the consultation on the draft guideline or update, and, if so, how has the committee considered and addressed them?

5) Protected characteristics outlined in the Equality Act 2010

a. Age

No further issues were identified.

b. Disability

No further issues were identified.

c. Gender reassignment

No further issues were identified.

d. Marriage and civil partnership

No further issues were identified.

e. Pregnancy and maternity

No further issues were identified.

f. Race

No further issues were identified.

g. Religion or belief

No further issues were identified.

h. Sex

No further issues were identified.

i. Sexual orientation

No further issues were identified.

6) Socioeconomic deprivation

No further issues were identified.

7) Geographical area variation

No further issues were identified.

8) Inclusion health and vulnerable groups

No further issues were identified.

5.3 If any recommendations have changed after consultation, how could these changes impact on equality and health inequalities issues?

No changes to the recommendations that impacted the equality and health inequalities issues were made.

5.4 Following the consultation on the draft guideline and response to questions 4.1 and 5.2, have there been any further committee considerations of equality and health inequalities issues across the four dimensions that have been reflected in the final guideline?

Nothing in addition with the above considerations.

5.5 Please provide a summary of the key equality and health inequalities issues that should be highlighted in the guidance executive report before sign-off of the final guideline or update

Key issues considered in this update related to the importance of:

- Using inclusive language for recommendations around adjuvant endocrine therapy. Separate recommendations were made for people with female reproductive organs and those with male reproductive organs.
- Promoting shared decision making by:
  - including cross references to the sections on communication in the NICE guidelines on [patient experience in adult NHS services \(CG138\)](#) and [shared decision making NICE guideline \(NG197\)](#).
  - including in recommendations the need to discuss the benefits and risks of the possible neoadjuvant chemotherapy or adjuvant endocrine therapy options with patients and taking people's circumstances, needs and preferences into account.
  - providing tables to be used by clinicians to support these discussions around taking the platinum based neoadjuvant chemotherapy for people with triple negative breast cancer, and around suitable adjuvant endocrine therapy regimens for people with female reproductive organs.
- Promoting research using real world evidence to fill gaps on the evidence base for specific groups of people as to the effectiveness of:

- testicular function suppression and around the types and severity of side effects experienced by people with ER-positive invasive or metastatic breast cancer, who have male reproductive organs.
- adding a platinum to a neoadjuvant chemotherapy regimen in people with invasive breast cancer that is triple negative and/or with a germline BRCA mutation who are aged 65 years and older, or pregnant or have male reproductive organs.

**Completed by developer:** Yolanda Martinez and Marie Harrisingh

**Date:** 17/03/2025

**Approved by committee chair:** Adam Firth

**Date:** 18/3/25

**Approved by NICE quality assurance lead:** Kate Kelley

**Date:** 03/04/25