

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Guideline scope

Menopause (update)

August 2022: This scope has been amended. This is to clarify that the guideline will not cover management of menopause-like symptoms resulting from hormone therapies for treatment of medical conditions other than cancer.

This guideline will update the NICE guideline on menopause: diagnosis and management (NG23).

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

1 Why the update is needed

New evidence that could affect recommendations was identified through the surveillance process. Full details are set out in the [surveillance review decisions from 2019](#) and [2021](#).

Stakeholders asked NICE to consider evidence on testosterone for managing symptoms associated with the menopause. The surveillance and scoping process did not identify any substantive new evidence on using testosterone beyond current recommendations in NG23. NICE has discussed the need for research in this area with the National Institute for Health and Care Research (NIHR) and has asked them to fund urgent research in this area.

Why the guideline is needed

Key facts and figures

Menopause is the process when menstrual cycles stop. Menopause transition (or perimenopause) is the gradual transition from menstrual cycles changing to

stopping. Menopause usually occurs naturally in women, and in some non-binary and trans people, aged 45 to 55. The duration of the process varies, but typically lasts for a few years. Evidence estimates that 3% to 8% of people with menopause have early menopause (menopause transition starting between 40 and 44 years; [Luborsky et al. 2003](#), [Mishra et al. 2017](#)) and an estimated 1% have premature ovarian insufficiency (menopause transition starting before 40 years; [Coulam et al. 1986](#)). Sometimes menopause is caused by surgical removal of the ovaries before natural menopause has occurred.

Menopause can affect people in a variety of ways. Most experience some symptoms, although not everyone seeks medical treatment. Some people have troublesome symptoms that may significantly impact their daily life, and need treatment. Menopausal symptoms may last for a long time, with a median duration of 7 years ([Avis et al. 2015](#)). Common symptoms associated with menopause are vasomotor symptoms (hot flushes and night sweats) and vaginal dryness. Other symptoms include changes to sleep and mood. Symptoms and their duration may vary between people from different ethnic groups ([Green and Santoro 2009](#); [Avis et al. 2015](#)). It can be difficult to differentiate between the impact of ageing and menopause. Some studies have shown that menopause may affect bone and cardiovascular health, increasing the risk of osteoporosis and cardiovascular disease.

There can be notable personal costs for those experiencing troublesome symptoms associated with the menopause. Most people experiencing menopause are of working age and troublesome symptoms may have an impact on work, including the need to take time off work. This can also have a notable effect on wider society.

Current practice

Not everyone needs medical treatment to manage the menopause. However, for those who do, there is variation in access to treatment and specialist services across the country. A range of effective interventions are available to manage troublesome symptoms depending on the circumstances and personal preferences. It is important to consider the short- and long-term benefits and risks of such treatments.

Policy, legislation, regulation and commissioning

In 2019 the Medicines and Healthcare products Regulatory Agency (MHRA) published a drug safety update on hormone replacement therapy based on the [Collaborative Group on Hormonal Factors in Breast Cancer's 2019 meta-analysis of type and timing of menopausal hormone therapy and breast cancer risk](#). Some of the conclusions on risk of breast cancer differ from the conclusions of the 2015 NICE guideline (NG23). Therefore, a review of new evidence is warranted. More information about this is provided in the [2019 surveillance of menopause: diagnosis and management \(NICE guideline NG23\)](#).

2 Who the guideline is for

This guideline is for:

- healthcare professionals who care for women, non-binary and trans people with menopause
- women, non-binary and trans people with menopause, their families or carers, and the public.

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](#).

Equality considerations

NICE has carried out an [equality impact assessment](#) during scoping. The assessment:

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

The guideline will look at inequalities relating to protected characteristics or other characteristics that might impact people's access to care, their experience of care and their menopause process, such as age, disability, ethnicity, socioeconomic status, and gender identity.

3 What the updated guideline will cover

3.1 Who is the focus?

Groups that will be covered in the update

- Women, non-binary and trans people with menopause aged 40 and older (including perimenopause and postmenopause).

3.2 Settings

Settings that will be covered

- All settings where NHS-commissioned care for menopause is provided.

3.3 Activities, services or aspects of care

Key areas that will be covered in this update

We will look at evidence in the areas below when developing this update. We will consider making new recommendations or updating existing recommendations in these areas only.

- 1 Managing troublesome menopausal symptoms.
 - Cognitive behavioural therapy to manage symptoms associated with the menopause.
 - Interventions to manage genitourinary symptoms associated with the menopause.
- 2 Effects of hormone replacement therapy on overall health outcomes.

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

Proposed outline for the guideline

The table below outlines all the areas that will be included in the guideline. It sets out what NICE plans to do for each area in this update.

Proposed outline for the guideline

Area of care	What NICE plans to do and why
1.1 Individualised care	<p>No evidence review: retain recommendations from existing guideline.</p> <p>This is because no substantive new evidence in this area was identified through the surveillance and scoping process.</p>
1.2 Diagnosis of perimenopause and menopause	<p>No evidence review: retain recommendations from existing guideline.</p> <p>This is because no substantive new evidence in this area was identified through the surveillance and scoping process.</p>
1.3 Information and advice	<p>No evidence review: retain recommendations from existing guideline.</p> <p>This is because no substantive new evidence in this area was identified through the surveillance and scoping process.</p>
1.4 Managing short-term menopausal symptoms:	
Vasomotor symptoms (hot flushes and night sweats)	<p>Review evidence on cognitive behavioural therapy: update existing recommendations as needed.</p> <p>This is because the surveillance and scoping process identified new evidence on cognitive behavioural therapy that may affect existing recommendations in NG23.</p>
Psychological symptoms	<p>Review evidence on cognitive behavioural therapy: update existing recommendations as needed.</p> <p>This is because the surveillance and scoping process identified new evidence on cognitive behavioural therapy that may affect existing recommendations in NG23.</p>
Altered sexual function	<p>No evidence review: retain recommendations from existing guideline.</p> <p>This is because no substantive new evidence in this area was identified through the surveillance and scoping process.</p>

Urogenital atrophy	<p>Review evidence: update existing recommendations as needed.</p> <p>This is because the surveillance and scoping process identified new evidence that may affect existing recommendations in NG23.</p>
Complementary therapies and unregulated preparations	<p>No evidence review: retain recommendations from existing guideline.</p> <p>This is because no substantive new evidence in this area was identified through the surveillance and scoping process.</p>
Review and referral	<p>No evidence review: retain recommendations from existing guideline.</p> <p>This is because no substantive new evidence in this area was identified through the surveillance and scoping process.</p>
Starting and stopping hormone replacement therapy	<p>No evidence review: retain recommendations from existing guideline.</p> <p>This is because no substantive new evidence in this area was identified through the surveillance and scoping process.</p>
Women with, or at high risk of, breast cancer	<p>Review evidence on cognitive behavioural therapy: update existing recommendations as needed.</p> <p>This is because the surveillance and scoping process identified new evidence on cognitive behavioural therapy for managing hot flushes in people with breast cancer that may affect existing recommendations in NG23.</p>
1.5 Long-term benefits and risks of hormone replacement therapy:	
Venous thromboembolism	<p>Review evidence for people with early menopause (40 to 44 years): update existing recommendations as needed.</p> <p>This is because the recommendations in NG23 are for people with menopausal symptoms. There is a need to review evidence on the overall health impact of hormone replacement therapy, including on venous thromboembolism, in people with early menopause (with or without menopausal symptoms).</p>
Cardiovascular disease	<p>Review evidence: update existing recommendations as needed.</p>

	<p>This is because the recommendations in NG23 are for people with menopausal symptoms. There is a need to review evidence on the overall health impact of hormone replacement therapy, including on cardiovascular disease, in people with early menopause (with or without menopausal symptoms). There is also a need to further review the evidence to address the needs of people with menopausal symptoms who are over 60 and considering hormone replacement therapy.</p>
Type 2 diabetes	<p>Review evidence for people with early menopause (40 to 44 years): update existing recommendations as needed.</p> <p>This is because the recommendations in NG23 are for people with menopausal symptoms. There is a need to review evidence on the overall health impact of hormone replacement therapy, including on type 2 diabetes, in people with early menopause (with or without menopausal symptoms).</p>
Breast cancer	<p>Review evidence: update existing recommendations as needed.</p> <p>This is because the surveillance and scoping process identified new evidence that may affect existing recommendations in NG23.</p>
Endometrial cancer	<p>Review evidence: new area in the guideline.</p> <p>This was included in the Medicine and Healthcare products Regulatory Agency (MHRA) drug safety update on hormone replacement therapy (2019) and was not covered in NG23.</p>
Ovarian cancer	<p>Review evidence: new area in the guideline.</p> <p>This was included in the MHRA drug safety update on hormone replacement therapy (2019) and was not covered in NG23.</p>
Osteoporosis	<p>Review evidence for people with early menopause (40 to 44 years): update existing recommendations as needed.</p> <p>This is because the recommendations in NG23 are for people with menopausal symptoms. There is a need to review evidence on the overall health impact of hormone replacement therapy, including on osteoporosis, in people with early</p>

	menopause (with or without menopausal symptoms).
Dementia	Review evidence: update existing recommendations as needed. This is because the surveillance and scoping process identified new evidence that may affect existing recommendations in NG23.
Loss of muscle mass and strength	Review evidence for people with early menopause (40 to 44 years): update existing recommendations as needed. This is because the recommendations in NG23 on hormone replacement therapy are for people with menopausal symptoms. There is a need to review evidence on the overall health impact of hormone replacement therapy, including on loss of muscle mass and strength, in people with early menopause (with or without menopausal symptoms).
All-cause mortality	Review evidence: new area in the guideline. There is a need to review evidence on all-cause mortality to consider the balance between the benefits and risks of hormone replacement therapy. This may help people decide whether they want to take hormone replacement therapy.
1.6 Diagnosing and managing premature ovarian insufficiency:	
Diagnosing premature ovarian insufficiency	No evidence review: retain recommendations from existing guideline. This is because no substantive new evidence in this area was identified through the surveillance and scoping process.
Managing premature ovarian insufficiency	No evidence review: retain recommendations from existing guideline. This is because no substantive new evidence in this area was identified through the surveillance and scoping process.

Recommendations in areas that are being retained from the existing guideline may be edited to ensure that they meet current editorial standards, and reflect the current policy and practice context.

Areas that will not be covered by the guideline

- Managing menopause-like symptoms in trans and non-binary people who are taking cross-sex hormones for treatment of gender dysphoria, including those who are medically transitioning
- Managing menopause-like symptoms resulting from hormone therapies for treatment of medical conditions other than cancer.

Related NICE guidance

Published

- [Transvaginal laser therapy for urogenital atrophy](#) (2021) NICE interventional procedures guidance IPG697
- [Familial breast cancer](#) (2013, updated 2019) NICE guideline CG164
- [Early and locally advanced breast cancer](#) (2018) NICE guideline NG101
- [Ovarian cancer: recognition and initial management](#) (2011) NICE guideline CG122

In development

- [Removal, preservation and subsequent re-implantation of ovarian tissue to delay the menopause](#). NICE interventional procedures guidance. Publication expected September 2022.
- [Ovarian cancer: identifying and managing familial and genetic risk](#). NICE guideline. Publication expected March 2024.

NICE guidance that will be updated by this guideline

- [Early and locally advanced breast cancer](#) (2018) NICE guideline NG101. An update of the recommendations on menopausal symptoms in section 1.12 will be considered.
- [Familial breast cancer](#) (2013, updated 2019) NICE guideline CG164. An update of the recommendations on hormone replacement therapy in section 1.7 will be considered.

NICE guidance about the experience of people using NHS services

NICE has produced the following guidance on the experience of people using the NHS. This guideline will not include additional recommendations on these topics unless there are specific issues related to menopause:

- [Shared decision making](#) (2021) NICE guideline NG197
- [Medicines optimisation](#) (2015) NICE guideline NG5
- [Patient experience in adult NHS services](#) (2012, updated 2021) NICE guideline CG138
- [Service user experience in adult mental health](#) (2011) NICE guideline CG136
- [Medicines adherence](#) (2009) NICE guideline CG76

3.4 Economic aspects

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

3.5 Key issues and draft questions

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

- 1 Managing troublesome menopausal symptoms
 - 1.1 What is the effectiveness of cognitive behavioural therapy for managing symptoms associated with the menopause?
 - 1.2 What is the effectiveness of treatments such as local oestrogen, ospemifene, prasterone and transvaginal laser therapy for managing genitourinary symptoms associated with the menopause?
- 2 Effects of hormone replacement therapy on overall health outcomes
 - 2.1 What are the effects of hormone replacement therapy for menopausal symptoms on developing cardiovascular disease?

2.2 What are the effects of hormone replacement therapy for menopausal symptoms on developing breast cancer?

2.3 What are the effects of hormone replacement therapy for menopausal symptoms on developing endometrial cancer?

2.4 What are the effects of hormone replacement therapy for menopausal symptoms on developing ovarian cancer?

2.5 What are the effects of hormone replacement therapy for menopausal symptoms on developing dementia?

2.6 What are the effects of hormone replacement therapy for menopausal symptoms on all-cause mortality?

2.7 What are the effects of hormone replacement therapy taken by people with early menopause (aged 40 to 44) on all-cause mortality and developing:

- venous thromboembolism
- cardiovascular disease
- type 2 diabetes
- breast cancer
- endometrial cancer
- ovarian cancer
- osteoporosis
- dementia
- loss of muscle mass and strength?

The key issues and draft questions will be used to develop more detailed review questions, which guide the systematic review of the literature.

3.6 Main outcomes

The main outcomes that may be considered when searching for and assessing the evidence are:

- health-related quality of life
- NICE guideline: menopause final scope (May 2022)

- genitourinary symptoms associated with the menopause
- low mood (not clinical depression)
- anxiety
- sleep disturbance
- vasomotor symptoms
- treatment-related adverse events
- all-cause mortality
- breast cancer incidence
- endometrial cancer incidence
- ovarian cancer incidence
- dementia or cognitive impairment
- cardiovascular disease
- type 2 diabetes
- osteoporosis
- loss of muscle mass and strength.

4 NICE quality standards

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

- [Menopause](#) (2017) NICE quality standard QS143

Further information

This is the final scope, which takes into account comments from registered stakeholders during consultation.

The guideline is expected to be published in August 2023.

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

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