

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Guideline scope

Menopause (update)

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](#).

Where this scope uses the term ‘women’, this should be taken to include trans and non-binary people who do not identify as women but who are likely to go through the menopause.

1 Why the update is needed

New evidence that could affect recommendations was identified through the surveillance process. Topic experts, including those who helped to develop the existing guideline, advised NICE on whether areas should be updated or new areas added. Full details are set out in the [surveillance review decisions from 2019 and 2021](#).

Why the guideline is needed

Key facts and figures

Menopause is the natural process when menstrual cycles stop. This is usually a gradual transition. It usually occurs in women aged 45 to 55 and typically lasts for a few years, sometimes longer. An estimated 3% to 8% of women experience early menopause (between 40 and 44 years, [Luborsky et al. 2003](#), [Mishra et al. 2017](#)) and an estimated 1% of women experience premature ovarian insufficiency (before 40 years, [Coulam et al. 1986](#)).

1 Menopause can affect people in a variety of ways. Not everyone experiences
2 menopausal symptoms. Most experience some symptoms, and some have
3 troublesome symptoms that may significantly impact their daily life. Menopausal
4 symptoms may last for a long time with an average duration of 7 years ([Avis et al.
5 2015](#)). The most common symptoms associated with menopause are vasomotor
6 symptoms (hot flushes and night sweats) and vaginal dryness. Symptoms may vary
7 between different ethnic backgrounds ([Green and Santoro 2009](#)).

8 Menopause is a natural part of ageing in women and it is difficult to differentiate
9 between the impact of ageing and menopause. Some studies have shown that
10 menopause may affect bone and cardiovascular health, increasing the risk of
11 osteoporosis and cardiovascular disease.

12 There may be significant personal and societal costs for those experiencing
13 troublesome symptoms associated with the menopause resulting in, for example,
14 more time off work.

15 **Current practice**

16 Not everyone needs medical treatment to manage the menopause. A range of
17 effective interventions are available to manage troublesome symptoms depending on
18 the circumstances and personal preferences. It is important to consider the short-
19 and long-term benefits and risks of such treatments.

20 **Policy, legislation, regulation and commissioning**

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

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 (including perimenopause and postmenopause).

Specific consideration will be given to:

- women, non-binary and trans people with menopause who have breast cancer
- women, non-binary and trans people with menopause who have familial risk of breast cancer.

1 **Groups that will not be covered in the update**

- 2 • Women, non-binary and trans people with premature ovarian insufficiency.

3 **3.2 Settings**

4 **Settings that will be covered**

- 5 • All settings where NHS-commissioned care is provided.

6 **3.3 Activities, services or aspects of care**

7 **Key areas that will be covered in this update**

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

- 11 1 Managing troublesome menopausal symptoms.
12 – Cognitive behavioural therapy to manage vasomotor symptoms (hot flushes
13 and night sweats) and psychological symptoms associated with the
14 menopause.
15 – Interventions to manage genitourinary symptoms associated with the
16 menopause.
17 2 Effects of hormone replacement therapy on overall health outcomes.

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

23 **Proposed outline for the guideline**

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

1 Proposed outline for the guideline

Area of care	What NICE plans to do
1.1 Individualised care	No evidence review: retain recommendations from existing guideline
1.2 Diagnosis of perimenopause and menopause	No evidence review: retain recommendations from existing guideline
1.3 Information and advice	No evidence review: retain recommendations from existing guideline
1.4 Managing short-term menopausal symptoms:	
Vasomotor symptoms (hot flushes and night sweats)	Review evidence on cognitive behavioural therapy: update existing recommendations as needed
Psychological symptoms	Review evidence on cognitive behavioural therapy: update existing recommendations as needed
Altered sexual function	No evidence review: retain recommendations from existing guideline
Urogenital atrophy	Review evidence: update existing recommendations as needed
Complementary therapies and unregulated preparations	No evidence review: retain recommendations from existing guideline
Review and referral	No evidence review: retain recommendations from existing guideline
Starting and stopping hormone replacement therapy	No evidence review: retain recommendations from existing guideline
Women with, or at high risk of, breast cancer	Review evidence on cognitive behavioural therapy: update existing recommendations as needed
1.5 Long-term benefits and risks of hormone replacement therapy:	
Venous thromboembolism	Review evidence for women, non-binary and trans people with early menopause (40 to 44 years): update existing recommendations as needed
Cardiovascular disease	Review evidence: update existing recommendations as needed
Type 2 diabetes	Review evidence for women, non-binary and trans people with early menopause (40 to 44 years): update existing recommendations as needed
Breast cancer	Review evidence: update existing recommendations as needed
Endometrial cancer	Review evidence: new area in the guideline

Ovarian cancer	Review evidence: new area in the guideline
Osteoporosis	Review evidence for women, non-binary and trans people with early menopause (40 to 44 years): update existing recommendations as needed
Dementia	Review evidence: update existing recommendations as needed
Loss of muscle mass and strength	Review evidence for women, non-binary and trans people with early menopause (40 to 44 years): update existing recommendations as needed
All-cause mortality	Review evidence: new area in the guideline
1.6 Diagnosing and managing premature ovarian insufficiency:	
Diagnosing premature ovarian insufficiency	No evidence review: retain recommendations from existing guideline
Managing premature ovarian insufficiency	No evidence review: retain recommendations from existing guideline

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

5 **Related NICE guidance**

6 **Published**

- 7 • [Transvaginal laser therapy for urogenital atrophy](#) (2021) NICE interventional
8 procedures guidance IPG697
- 9 • [Familial breast cancer](#) (2013, updated 2019) NICE guideline CG164
- 10 • [Early and locally advanced breast cancer](#) (2018) NICE guideline NG101
- 11 • [Raloxifene and teriparatide for the secondary prevention of osteoporotic fragility
12 fractures in postmenopausal women](#) (2008, updated 2018) NICE technology
13 appraisal guidance TA161

1 **In development**

- 2 • [Removal, preservation and subsequent re-implantation of ovarian tissue to delay](#)
3 [the menopause](#). NICE interventional procedures guidance. Publication date to be
4 confirmed.

5 **NICE guidance that will be updated by this guideline**

- 6 • [Early and locally advanced breast cancer](#) (2018) NICE guideline NG101. A refresh
7 of recommendation 1.12.12 will be considered, to include a link to this updated
8 guideline.
- 9 • [Familial breast cancer](#) (2013, updated 2019) NICE guideline CG164. A refresh of
10 recommendation 1.7.14 will be considered, to include a link to this updated
11 guideline.

12 **NICE guidance about the experience of people using NHS services**

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

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

22 **3.4 Economic aspects**

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

1 **3.5 Key issues and draft questions**

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

4 1 Managing troublesome menopausal symptoms

5 1.1 What is the effectiveness of cognitive behavioural therapy for
6 managing vasomotor symptoms (hot flushes and night sweats) and
7 psychological symptoms associated with the menopause?

8 1.2 What the effectiveness of treatments such as local oestrogen,
9 ospemifene, prasterone and transvaginal laser therapy for managing
10 genitourinary symptoms associated with the menopause?

11 2 Effects of hormone replacement therapy on overall health outcomes

12 2.1 What are the effects of hormone replacement therapy for menopausal
13 symptoms on developing cardiovascular disease?

14 2.2 What are the effects of hormone replacement therapy for menopausal
15 symptoms on developing breast cancer?

16 2.3 What are the effects of hormone replacement therapy for menopausal
17 symptoms on developing endometrial cancer?

18 2.4 What are the effects of hormone replacement therapy for menopausal
19 symptoms on developing ovarian cancer?

20 2.5 What are the effects of hormone replacement therapy for menopausal
21 symptoms on developing dementia?

22 2.6 What are the effects of hormone replacement therapy for menopausal
23 symptoms on all-cause mortality?

24 2.7 What are the effects of hormone replacement therapy taken by
25 women, non-binary and trans people with early menopause (aged 40 to
26 44) on all-cause mortality and developing:

- 27 • venous thromboembolism

- 1 • cardiovascular disease
- 2 • type 2 diabetes
- 3 • breast cancer
- 4 • endometrial cancer
- 5 • ovarian cancer
- 6 • osteoporosis
- 7 • dementia
- 8 • loss of muscle mass and strength?

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

11 **3.6 Main outcomes**

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

- 14 • health-related quality of life
- 15 • genitourinary symptoms associated with the menopause
- 16 • low mood (not clinical depression)
- 17 • anxiety
- 18 • sleep disturbance
- 19 • vasomotor symptoms
- 20 • treatment-related adverse events
- 21 • all-cause mortality
- 22 • breast cancer incidence
- 23 • endometrial cancer incidence
- 24 • ovarian cancer incidence
- 25 • dementia or cognitive impairment
- 26 • cardiovascular disease
- 27 • type 2 diabetes
- 28 • osteoporosis
- 29 • loss of muscle mass and strength.

1 **4 NICE quality standards**

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

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

5 **Further information**

This is the draft scope for consultation with registered stakeholders. The consultation dates are 8 February to 8 March 2022.

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.

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