

1 **Why the guideline is needed**

2 Please see original [scope for NG12](#) and [scope for NG131](#).

3 **2 Who the guidelines are for**

4 This guideline is for:

- 5 • healthcare professionals in the NHS
- 6 • commissioners and providers of prostate cancer services
- 7 • people using services and their families and carers.

8 It may also be relevant for:

- 9 • voluntary organisations and patient support groups.

10 NICE guidelines cover health and care in England. Decisions on how they
11 apply in other UK countries are made by ministers in the [Welsh Government](#),
12 [Scottish Government](#) and [Northern Ireland Executive](#).

13 **Equality considerations**

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

15 The assessment:

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

18 **3 What the updated guidelines will cover**

19 **3.1 Who is the focus?**

20 **Groups that will be covered (NG12)**

- 21 • People presenting to primary care with signs or symptoms of suspected
22 cancer.

Suspected cancer: recognition and referral (update). Prostate cancer:
diagnosis and management (update).

1 **Groups that will be covered (NG131)**

- 2 • People referred from primary care for investigation of possible prostate
3 cancer, in line with [NICE guideline on suspected cancer: recognition and](#)
4 [referral](#) (2021).
- 5 • People with a confirmed diagnosis of primary adenocarcinoma of the
6 prostate or, if biopsy is inappropriate, an agreed clinical diagnosis (based
7 on, for example, digital rectal examination, high prostate-specific antigen
8 [PSA] levels or known metastases).

9 **Groups that will not be covered (NG12)**

- 10 • People who do not have signs or symptoms of suspected cancer.
- 11 • People who have been referred to secondary care for specialist
12 management.
- 13 • People who present for the first time outside of primary care.

14 **Groups that will not be covered (NG131)**

- 15 • People who are asymptomatic and have an abnormal PSA level who are
16 not referred for subsequent investigation.
- 17 • People with metastatic disease of different primary origin involving the
18 prostate.
- 19 • People with rare malignant tumours of the prostate, such as small-cell
20 carcinoma and rhabdomyosarcoma.

21 **3.2 Settings**

22 **Settings that will be covered (NG12 and NG131)**

- 23 • All settings where NHS services are provided.

Suspected cancer: recognition and referral (update). Prostate cancer:
diagnosis and management (update).

1 **3.3 Activities, services or aspects of care**

2 **Key areas that will be covered in this update (NG12)**

3 For the update to NG12 we will look at evidence on suspected prostate cancer
4 referral. We will consider making new recommendations or updating existing
5 recommendations in this area only.

6 **Key areas that will be covered in this update (NG131)**

7 For the update to NG131 we will look at evidence on risk stratification of
8 localised or locally advanced prostate cancer, which falls under staging in the
9 current guideline. We will consider making new recommendations or updating
10 existing recommendations for this area only.

11 However, the impact of any changes in this area on related recommendations
12 may need to be considered and recommendations in other sections of the
13 guideline may need to be amended. This is detailed in table 2 in the proposed
14 outline for the guideline section.

15 **Proposed outline for the guideline (NG12)**

16 The table below outlines the areas in the existing [NICE guideline on](#)
17 [suspected cancer: recognition and referral](#) (2021) that will be updated from
18 this scope. It sets out what NICE plans to do for each area in this update.

19 **Table 1: What NICE plans to do for each area in the NICE guideline on**
20 **suspected cancer: recognition and referral (2021)**

Area in the guideline (NG12)	What NICE plans to do
1.1 Lung and pleural cancers	No evidence review: retain recommendations from existing guideline.
1.2 Upper gastrointestinal tract cancers	No evidence review: retain recommendations from existing guideline.
1.3 Lower gastrointestinal tract cancers	No evidence review: retain recommendations from existing guideline.

Suspected cancer: recognition and referral (update). Prostate cancer: diagnosis and management (update).

1.4 Breast cancer	No evidence review: retain recommendations from existing guideline.
1.5 Gynaecological cancers	No evidence review: retain recommendations from existing guideline.
1.6 Urological cancers	No evidence review: retain recommendations from existing guideline.
Prostate cancer	Review evidence: update recommendation 1.6.3 in the current guideline as appropriate
Bladder cancer	No evidence review: retain recommendations from existing guideline.
Renal cancer	No evidence review: retain recommendations from existing guideline.
Testicular cancer	No evidence review: retain recommendations from existing guideline.
Penile cancer	No evidence review: retain recommendations from existing guideline.
1.7 Skin cancers	No evidence review: retain recommendations from existing guideline.
1.8 Head and neck cancers	No evidence review: retain recommendations from existing guideline.
1.9 Brain and central nervous system cancers	No evidence review: retain recommendations from existing guideline.
1.10 Haematological cancers	No evidence review: retain recommendations from existing guideline.
1.11 Sarcomas	No evidence review: retain recommendations from existing guideline.
1.12 Childhood cancers	No evidence review: retain recommendations from existing guideline.
1.13 Non-site-specific symptoms	No evidence review: retain recommendations from existing guideline.

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2 **Proposed outline for the guideline (NG131)**

3 The table below outline the areas in the existing [NICE guideline on prostate](#)
4 [cancer: diagnosis and management](#) (2019) that will be updated from this
5 scope. It sets out what NICE plans to do for each area in this update.

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Suspected cancer: recognition and referral (update). Prostate cancer: diagnosis and management (update).

Table 1 What NICE plans to do for each area in the NICE guideline on prostate cancer: diagnosis and management (2019)

Area in the guideline (NG131)	What NICE plans to do
1.1 Information and decision support for people with prostate cancer, their partners and carers	
Information	No evidence review: retain recommendations from existing guideline.
Decision support	No evidence review: retain recommendations from existing guideline.
1.2 Assessment and diagnosis	
Magnetic resonance imaging and biopsy	No evidence review: retain recommendations from existing guideline.
If the MRI or biopsy is negative	No evidence review: retain recommendations from existing guideline.
Staging	Review evidence: update existing recommendations as needed.
1.3 Localised and locally advanced prostate cancer	
Low-risk localised prostate cancer	No review of the evidence: amend the recommendations if needed to align with any update to the staging recommendations.
Multiparametric MRI and protocol for active surveillance	No evidence review: retain recommendations from existing guideline.
Intermediate-risk localised prostate cancer	No review of the evidence: amend the recommendations if needed to align with any update to the staging recommendations.
High-risk localised prostate cancer	No review of the evidence: amend the recommendations if needed to align with any update to the staging recommendations.
Radical treatment	No review of the evidence: amend the recommendations if needed to align with any update to the staging recommendations.
Watchful waiting	No evidence review: retain recommendations from existing guideline.
Locally advanced prostate cancer	No evidence review: retain recommendations from existing guideline.
Managing adverse effects of radical treatment	No evidence review: retain recommendations from existing guideline.

Suspected cancer: recognition and referral (update). Prostate cancer: diagnosis and management (update).

Sexual dysfunction	No evidence review: retain recommendations from existing guideline.
Urinary incontinence	No evidence review: retain recommendations from existing guideline.
Radiation-induced enteropathy	No evidence review: retain recommendations from existing guideline.
Follow-up for people with localised or locally advanced prostate cancer having radical treatment or on watchful waiting	No evidence review: retain recommendations from existing guideline.
Managing relapse after radical treatment	No evidence review: retain recommendations from existing guideline.
1.4 People having hormone therapy	
Managing adverse effects of hormone therapy	No evidence review: retain recommendations from existing guideline.
Hot flushes	No evidence review: retain recommendations from existing guideline.
Sexual dysfunction	No evidence review: retain recommendations from existing guideline.
Osteoporosis	No evidence review: retain recommendations from existing guideline.
Gynaecomastia	No evidence review: retain recommendations from existing guideline.
Fatigue	No evidence review: retain recommendations from existing guideline.
1.5 Metastatic prostate cancer	
Information and support	No evidence review: retain recommendations from existing guideline.
Initial treatment	No evidence review: retain recommendations from existing guideline.
Hormone-relapsed metastatic prostate cancer	No evidence review: retain recommendations from existing guideline.
Bone-targeted therapies	No evidence review: retain recommendations from existing guideline.
Pelvic-targeted therapies	No evidence review: retain recommendations from existing guideline.

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2 **Areas that will not be covered (NG12)**

- 3 1. The organisation or effectiveness of screening programmes for cancer.
- 4 2. Referral for suspected recurrence or metastases in previously diagnosed
- 5 cancer or for palliative care.

Suspected cancer: recognition and referral (update). Prostate cancer: diagnosis and management (update).

1 **Areas that will not be covered (NG131)**

- 2 1. Referral from primary care with suspected prostate cancer - this is
3 covered by the NICE guideline on suspected cancer: recognition and
4 referral (2021).
- 5 2. Screening for prostate cancer - this is covered by the UK National
6 Screening Committee.

7 **3.4 Economic aspects**

8 We will take economic aspects into account when making recommendations.
9 We will review the economic evidence using an NHS, public sector and other
10 perspectives, as appropriate.

11 **3.5 Review questions**

12 While writing the scope for these guidelines for update, we have identified the
13 following review questions related to them:

- 14 1. Suspected prostate cancer referral (NG12).
 - 15 1.1 In people with suspected prostate cancer with any of the
16 following symptoms - any lower urinary tract symptoms (such as
17 nocturia, urinary frequency, hesitancy, urgency or retention),
18 erectile dysfunction or visible haematuria; what is the diagnostic
19 accuracy of PSA test thresholds compared with age-adjusted PSA
20 thresholds?
- 21 2. Staging (NG131).
 - 22 2.1 In people with localised or locally advanced prostate cancer,
23 which risk stratification models/tools/categorising systems perform
24 better in indicating risk of poor outcomes?

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Suspected cancer: recognition and referral (update). Prostate cancer:
diagnosis and management (update).

1 3.6 PICO tables for the review questions

2 For the update of NICE guideline on suspected cancer: recognition 3 and referral (2021)

4 Table 2: PICO table for diagnostic accuracy of PSA tests in people with 5 suspected prostate cancer

Review question	<ul style="list-style-type: none"> In people with suspected prostate cancer, with any of the following symptoms - any lower urinary tract symptoms (such as nocturia, urinary frequency, hesitancy, urgency or retention), erectile dysfunction or visible haematuria; what is the diagnostic accuracy of fixed PSA test thresholds compared with age-adjusted PSA thresholds?
Population	<p>Adults with suspected prostate cancer with the following symptoms:</p> <ul style="list-style-type: none"> any lower urinary tract symptoms, such as nocturia, urinary frequency, hesitancy, urgency or retention or erectile dysfunction or visible haematuria
Test	<p>Diagnostic accuracy studies</p> <ul style="list-style-type: none"> Age-adjusted PSA test PSA test (without age adjustment - fixed test threshold)
Reference standard	<ul style="list-style-type: none"> Multiparametric MRI scan Prostate biopsy
Outcomes	<p>Diagnostic accuracy metrics</p> <ul style="list-style-type: none"> Positive and negative likelihood ratios

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	<ul style="list-style-type: none"> • Positive and negative predictive values • Sensitivity and specificity
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2 **For the update of the NICE guideline on prostate cancer: diagnosis**
3 **and management (2019)**

4 **Table 4: PICO table for risk stratification for people with localised**
5 **prostate cancer**

Review question	In people with localised or locally advanced prostate cancer, which risk stratification models/tools/categorising systems perform better in indicating risk poor outcomes?
Population	People newly diagnosed with localised or locally advanced prostate cancer
Prognostic models	<ul style="list-style-type: none"> • 5-tier prostate cancer risk stratification tools (for example Cambridge Prognostic Group [CPG], Memorial Sloan Kettering Cancer Centre [MSKCC], Cancer of the Prostate Risk Assessment [CAPRA]) • 3-tier prostate cancer risk stratification tools (for example NICE's tool)
Outcomes	<p>Clinical endpoints</p> <ul style="list-style-type: none"> • Prostate cancer specific - mortality • Progression to metastatic prostate cancer • Progression-free survival • Metastasis-free survival • Health-related quality of life <p>For each outcome, the following metrics will be reported where available, for example:</p>

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	<ul style="list-style-type: none"> • Odds ratios/hazard ratios • Model fit statistics (for example R2, Brier score) • Discrimination (for example C statistic, area under ROC curve) • Calibration (for example calibration slope)
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1 **4 NICE quality standards and NICE Pathways**

2 **4.1 NICE quality standards**

3 **NICE quality standards that may need to be revised or updated** 4 **when this guideline is published**

- 5 • [Prostate Cancer. NICE quality standard QS91](#) (2019)

6 **4.2 NICE Pathways**

7 When this guideline is published, we will update the existing [NICE Pathway on](#)
8 [prostate cancer](#). NICE Pathways bring together everything NICE has said on
9 a topic in an interactive flowchart.

10 **5 Further information**

This is the draft scope.

The guideline is expected to be published: to be confirmed.

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

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

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Suspected cancer: recognition and referral (update). Prostate cancer:
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