

October 2020: This scope was amended to remove the 2 NICE cancer service guidelines – improving outcomes for people with skin tumours including melanoma (update): the management of low-risk basal cell carcinomas in the community (CSG8; 2010), and improving outcomes for people with skin tumours including melanoma: the manual (CSG8; 2006). These cancer service guidelines will be retained but not updated.

The update will only cover melanoma.

## NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

### Guideline scope

### Melanoma (update)

This guideline will update the NICE guideline on melanoma: assessment and management (NG14).

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

This guideline will also be used to update the [NICE quality standard for skin cancer](#).

#### **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 guidelines, advised NICE on whether areas should be updated or new areas added. Full details are set out in the [surveillance review decision](#).

As part of the scoping process, NICE has identified additional areas not included in the surveillance report, for which the evidence needs to be reviewed:

- Surgical and histological excision margins for people with stage 0 to 2 melanoma.
- Sentinel lymph node biopsy for people with stage 3 melanoma.
- Body imaging for the follow-up of people with stage 3 melanoma.
- Follow-up of people with stage 4 melanoma.

### ***Why the guideline is needed***

#### **Key facts and figures**

Melanoma is the third most common skin cancer in the UK. It accounts for more cancer deaths than all other skin cancers combined. In 2016, there were 16,374 new cases of melanoma and 2,209 deaths from melanoma. The UK incidence of melanoma skin cancer has increased by almost half (45%) over the last decade.

#### **Current practice**

The treatment for melanoma depends on the stage of the cancer, which is determined following assessment and staging investigations including sentinel lymph node biopsy and imaging. Treatments include surgical excision, imiquimod cream, completion lymphadenectomy, lymph node dissection, targeted treatments, immunotherapy, chemotherapy and radiotherapy. Regular follow-ups after treatment check for local recurrence, spread to other parts of the body and new primary melanomas.

Since the publication of the existing NICE guideline on melanoma: assessment and management (NG14), the 8th editions of the [Union for International Cancer Control \(UICC\) Tumour Node Metastasis \(TNM\)](#) and [American Joint Committee on Cancer \(AJCC\)](#) staging systems for melanoma have been published.

## **Policy, legislation, regulation and commissioning**

The [NHS long term plan for cancer](#) is committed to improving cancer outcomes and services in England over the next 10 years. Its key ambitions include increasing the proportion of cancers diagnosed at stage 1 and 2, and for more people each year to survive their cancer for at least 5 years after diagnosis. The NHS also sets out the ambition for all people with suspected cancer to have a diagnosis within 28 days of first seeing a doctor with symptoms. NHS England recently published [guidance for cancer alliances on streamlining multidisciplinary meetings](#).

## **2 Who the guideline is for**

This guideline is for:

- healthcare professionals in primary, secondary and tertiary care
- commissioners and providers of NHS-funded healthcare services
- people with melanoma and their families and carers.

It may also be relevant to providers of private healthcare services.

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.

## **3 What the updated guideline will cover**

### **3.1 *Who is the focus?***

#### **Groups that will be covered**

- People with cutaneous melanoma.

Specific consideration will be given to:

- Pregnant women.
- People with a compromised immune system.

#### **Groups that will not be covered**

- People with primary ocular melanoma.
- People with melanoma arising from mucosal sites. (Note that although for most melanoma cases it will be clear whether they arose from mucosal or cutaneous sites, for some it may be unclear.)
- People with skin cancer other than melanoma, for example, cutaneous squamous cell carcinoma, basal cell carcinoma, Merkel cell carcinoma and cutaneous lymphoma.

### **3.2 *Settings***

#### **Settings that will be covered**

All settings where NHS-funded care 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 Assessing melanoma
  - Genetic testing in early-stage melanoma
- 2 Staging investigations

- Sentinel lymph node biopsy
- Imaging
- 3 Managing stage 0 to 2 melanoma
  - Excision
- 4 Managing stage 3 melanoma
  - Completion lymphadenectomy
  - Lymph node dissection
  - Sentinel lymph node biopsy
  - Adjunctive systemic therapy (cross reference to NICE Pathway)
- 5 Managing stage 4 (and unresectable stage 3) melanoma
  - Systemic anticancer treatment
- 6 Follow-up after treatment for melanoma
  - Follow-up for all people who have had melanoma
  - Follow-up after stage 2C melanoma with no sentinel lymph node biopsy or stage 3 melanoma
  - Follow-up of stage 4 melanoma

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.

#### **Melanoma (NICE guideline NG14, published July 2015)**

<b>Area of care</b>	<b>What NICE plans to do</b>
1.1 Communication and support	
Communication and support	No evidence review: retain recommendations from existing guideline

1.2 Assessing melanoma	
Dermoscopy and other visualisation techniques	No evidence review: retain recommendations from existing guideline
Photography	No evidence review: retain recommendations from existing guideline
Assessing and managing atypical spitzoid lesions	No evidence review: retain recommendations from existing guideline
Taking tumour samples for genetic testing	No evidence review: retain recommendations from existing guideline
Genetic testing in early-stage melanoma	Review evidence: update existing recommendations 1.2.9 and 1.2.10 as needed
1.3 Managing suboptimal vitamin D levels	
Managing suboptimal vitamin D levels	No evidence review: retain recommendations from existing guideline
1.4 Managing concurrent drug treatment	
Managing concurrent drug treatment	No evidence review: retain recommendations from existing guideline
1.5 Staging investigations	
Sentinel lymph node biopsy	Review evidence: update existing recommendations 1.5.1 and 1.5.2 as needed
Imaging	Review evidence: update existing recommendations 1.5.3 to 1.5.5 as needed
1.6 Managing stage 0 to 2 melanoma	
Excision	Review evidence: update existing recommendations 1.6.1 to 1.6.4 as needed
Imiquimod for stage 0 melanoma	No evidence review: retain recommendations from existing guideline
1.7 Managing stage 3 melanoma	
Completion lymphadenectomy	Review evidence: update existing recommendation 1.7.1 as needed
Lymph node dissection	Review evidence: update existing recommendation 1.7.2 as needed
Sentinel lymph node biopsy	Review evidence: new area in the guideline
Adjuvant radiotherapy	No evidence review: retain recommendations from existing guideline

Adjunctive systemic therapy	No evidence review: a link to the NICE Pathway where technology appraisals appear will be added
Palliative treatment for in-transit metastases	No evidence review: retain recommendations from existing guideline
Palliative treatment for superficial skin metastases	No evidence review: retain recommendations from existing guideline
1.8 Managing stage 4 melanoma	
Management of oligometastatic stage 4 melanoma	No evidence review: retain recommendations from existing guideline
Brain metastases	No evidence review: retain recommendations from existing guideline
Systemic anticancer treatment – targeted treatments	Review evidence: update existing recommendations 1.8.5 and 1.8.6 as needed  For the update of section 1.8 of Melanoma (NICE guideline NG14, published July 2015), current NICE technology appraisal recommendations will be sequenced within the clinical context  A link to the NICE Pathway where technology appraisals appear will be added where relevant
Systemic anticancer treatment – immunotherapy	Review evidence: update existing recommendation 1.8.7 as needed  For the update of section 1.8 of Melanoma (NICE guideline NG14, published July 2015), current NICE technology appraisal recommendations will be sequenced within the clinical context  A link to the NICE Pathway where technology appraisals appear will be added where relevant
Systemic anticancer treatment – cytotoxic chemotherapy	Review evidence: update existing recommendations 1.8.8 and 1.8.9 as needed
1.9 Follow-up after treatment for melanoma	
Follow-up for all people who have had melanoma	Review evidence: update existing recommendations 1.9.1 to 1.9.9 as needed  Refer to the NICE guideline on brain tumours (primary) and brain metastases in adults (NG99)

Follow-up after stage 0 melanoma	No evidence review: retain recommendations from existing guideline
Follow-up after stage 1A melanoma	No evidence review: retain recommendations from existing guideline
Follow-up after stage 1B to 2B melanoma or stage 2C melanoma (fully staged using sentinel lymph node biopsy)	No evidence review: retain recommendations from existing guideline
Follow-up after stage 2C melanoma with no sentinel lymph node biopsy or stage 3 melanoma	Review evidence for body imaging: update existing recommendation 1.9.16 as needed No evidence review: retain recommendation 1.9.15 from existing guideline
Follow-up after stage 4 melanoma	Review evidence: update existing recommendation 1.9.17 as needed

Recommendations in areas that are being retained from the existing guidelines 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

- 1 Referral from primary care for people with suspected melanoma. This is covered by the [NICE guideline on suspected cancer: recognition and referral](#) (NG12).
- 2 Awareness and prevention of melanoma. This is covered by the [NICE guidelines on skin cancer prevention](#) (PH32) and [sunlight exposure: risk and benefits](#) (NG34).
- 3 End of life care. This is covered by the [NICE guideline on care of dying adults in the last days of life](#) (NG31).
- 4 Complementary therapies for the treatment of melanoma.
- 5 Assessment and management of skin tumours and cancers other than cutaneous melanoma.
- 6 Areas covered by the NICE guideline on [improving outcomes for people with skin tumours including melanoma \(update\): the management of low-risk basal cell carcinomas in the community](#) (2010) NICE guideline



CSG8 or the NICE guideline [improving outcomes for people with skin tumours including melanoma: the manual](#) (2006) NICE guideline CSG8.

## Related NICE guidance

### *Published*

- [COVID-19 rapid guideline: dermatological conditions treated with drugs affecting the immune response](#) (2020) NICE guideline NG169
- [Surgical site infections: prevention and treatment](#) (2019) NICE guideline NG125
- [Encorafenib with binimetinib for unresectable or metastatic BRAF V600 mutation-positive melanoma](#) (2019) NICE technology appraisal guidance 562
- [Nivolumab for adjuvant treatment of completely resected melanoma with lymph node involvement or metastatic disease](#) (2019) NICE technology appraisal guidance 558
- [Brain tumours \(primary\) and brain metastases in adults](#) (2018) NICE guideline NG99
- [Pembrolizumab for adjuvant treatment of resected melanoma with high risk of recurrence](#) (2018) NICE technology appraisal guidance 553
- [Dabrafenib with trametinib for adjuvant treatment of resected BRAF V600 mutation-positive melanoma](#) (2018) NICE technology appraisal guidance 544
- [Routine perioperative tests for elective surgery](#) (2016) NICE guideline NG45
- [Sunlight exposure: risks and benefits](#) (2016) NICE guideline NG34
- [Cobimetinib in combination with vemurafenib for treating unresectable or metastatic BRAF V600 mutation-positive melanoma](#) (2016) NICE technology appraisal guidance 414
- [Talimogene laherparepvec for treating unresectable metastatic melanoma](#) (2016) NICE technology appraisal guidance 410
- [Nivolumab in combination with ipilimumab for treating advanced melanoma](#) (2016) NICE technology appraisal guidance 400

- [Trametinib in combination with dabrafenib for treating unresectable or metastatic melanoma](#) (2016) NICE technology appraisal guidance 396
- [Nivolumab for treating advanced \(unresectable or metastatic\) melanoma](#) (2016) NICE technology appraisal guidance 384
- [Suspected cancer: recognition and referral](#) (2015) NICE guideline NG12
- [Pembrolizumab for advanced melanoma not previously treated with ipilimumab](#) (2015) NICE technology appraisal guidance 366
- [Pembrolizumab for treating advanced melanoma after disease progression with ipilimumab](#) (2015) NICE technology appraisal guidance 357
- [VivaScope 1500 and 3000 imaging systems for detecting skin cancer lesions](#) (2015) NICE diagnostics guidance 19
- [Vitamin D: supplement use in specific population groups](#) (2014) NICE guideline PH56
- [Dabrafenib for treating unresectable or metastatic BRAF V600 mutation-positive melanoma](#) (2014) NICE technology appraisal guidance 321
- [Ipilimumab for previously untreated advanced \(unresectable or metastatic\) melanoma](#) (2014) NICE technology appraisal guidance 319
- [Electrochemotherapy for metastases in the skin from tumours of non-skin origin and melanoma](#) (2013) NICE interventional procedures guidance 446
- [Psoriasis: assessment and management](#) (2012) NICE guideline CG153
- [Neutropenic sepsis: prevention and management in people with cancer](#) (2012) NICE guideline CG151
- [Palliative care for adults: strong opioids for pain relief](#) (2012) NICE guideline CG140
- [Vemurafenib for treating locally advanced or metastatic BRAF V600 mutation-positive malignant melanoma](#) (2012) NICE technology appraisal guidance 269
- [Ipilimumab for previously treated advanced \(unresectable or metastatic\) melanoma](#) (2012) NICE technology appraisal guidance 268
- [Skin cancer prevention](#) (2011) NICE guideline PH32
- [Endoscopic radical inguinal lymphadenectomy](#) (2011) NICE interventional procedures guidance 398

- [Metastatic malignant disease of unknown primary origin in adults: diagnosis and management](#) (2010) NICE guideline CG104
- [Improving outcomes for people with skin tumours including melanoma \(update\): the management of low-risk basal cell carcinomas in the community](#) (2010) NICE guideline CSG8
- [Improving outcomes for people with skin tumours including melanoma: the manual](#) (2006) NICE guideline CSG8
- [Improving outcomes in children and young people with cancer](#) (2005) NICE guideline CSG7
- [Improving supportive and palliative care for adults with cancer](#) (2004) NICE guideline CSG4

### ***In development***

- [Shared decision making](#). NICE guideline. Publication expected April 2021.
- [Babies, children and young people's experience of healthcare](#). NICE guideline. Publication expected April 2021.
- [Relatlimab with nivolumab for treating advanced malignant melanoma after immunotherapy in people over 12](#). NICE technology appraisal guidance. Publication date to be confirmed.
- [Nivolumab with ipilimumab for adjuvant treatment of completely resected stage III or IV melanoma](#). NICE technology appraisal guidance. Publication date to be confirmed.

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

- [Melanoma: assessment and management](#) (2015) NICE guideline NG14

### **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 melanoma:

- [Medicines optimisation](#) (2015) NICE guideline NG5
- [Patient experience in adult NHS services](#) (2012) NICE guideline CG138
- [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, public sector and other perspectives, 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 questions related to them:

- 1 Assessing melanoma
  - 1.1 What is the role and optimal timing of genetic testing of the tumour after diagnosis for a person with stage 2C to 3 melanoma?
- 2 Staging investigations
  - 2.1 What is the most accurate method of staging melanoma in people preliminarily assigned:
    - (a) clinicopathological stage 1A melanoma?
    - (b) clinicopathological stage 1B to 2C melanoma (including, but not limited to, sentinel lymph node biopsy)?
    - (c) clinicopathological stage 3 melanoma?
    - (d) clinicopathological stage 4 melanoma?
- 3 Managing stage 0 to 2 melanoma
  - 3.1 What are the most effective surgical and histological excision margins for stage 0 to 2 melanoma?
- 4 Managing stage 3 melanoma
  - 4.1 What is the most effective surgical treatment for stage 3 melanoma?
  - 4.2 What is the utility of sentinel lymph node biopsy for people with stage 3 melanoma and micro-satellite lesions?
- 5 Managing stage 4 (and unresectable stage 3) melanoma
  - 5.1 What is the most effective systemic and localised anticancer treatment for people with stage 4 (and unresectable stage 3) melanoma?

[Current NICE technology appraisal recommendations will be sequenced within the clinical context]

## 6 Follow-up after treatment for melanoma

6.1 After treatment with curative intent for melanoma, what is the optimal method, frequency, setting and duration of follow-up?

6.2 What is the effectiveness of body imaging for the follow-up of people with stage 2C (with no sentinel lymph node biopsy) and stage 3 melanoma, including the optimal frequency and duration?

6.3 Should brain imaging be included for people with melanoma who are undergoing body imaging as part of follow-up, and who have no neurological signs or symptoms?

6.4 What is the effectiveness of body imaging for the follow-up of people with stage 4 (and unresectable stage 3) melanoma after concluding treatment, including the optimal frequency and duration?

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:

- survival
- health-related quality of life
- recurrence and time to recurrence
- melanoma-related morbidity
- adverse events
- number and length of admissions to hospital after diagnosis.

## 4 NICE quality standards and NICE Pathways

### 4.1 *NICE quality standards*

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

- [Skin cancer](#) (2016) NICE quality standard 130.

### 4.2 *NICE Pathways*

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

## 5 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 April 2022.

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

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

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