



Guideline 8-2 Version 2

A Quality Initiative of the  
Program in Evidence-Based Care (PEBC), Cancer Care Ontario (CCO)

## Primary Excision Margins and Sentinel Lymph Node Biopsy in Cutaneous Melanoma

*F. Wright, L.H. Souter, S. Kellett, A. Easson, C. Murray, J. Toye, D. McCready, C. Nessim, D. Ghazarian, N. Look Hong, S. Johnson, D. Goldstein, T. Petrella, and the Melanoma Disease Site Group*

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An assessment conducted in November 2023 deferred the review of Guideline 8-2 Version 2. This means that the document remains current until it is assessed again next year. The PEBC has a formal and standardized process to ensure the currency of each document. ([PEBC Assessment & Review Protocol](#))

Guideline 8-2 Version 2 is comprised of 5 sections. You can access the summary and full report here:

<https://www.cancercareontario.ca/en/guidelines-advice/types-of-cancer/51116>

- Section 1: Recommendations
- Section 2: Guideline - Recommendations and Key Evidence
- Section 3: Guideline Methods Overview
- Section 4: Systematic Review
- Section 5: Internal and External Review

For information about this document, please contact Frances Wright,  
the lead author, through the PEBC via:

Phone: 905-527-4322 ext. 42822 Fax: 905 526-6775 E-mail: [ccopgi@mcmaster.ca](mailto:ccopgi@mcmaster.ca)

For information about the PEBC and the most current version of all reports, please visit the  
CCO website at <http://www.cancercare.on.ca/> or contact the PEBC office at:

Phone: 905-527-4322 ext. 42822 Fax: 905 526-6775 E-mail: [ccopgi@mcmaster.ca](mailto:ccopgi@mcmaster.ca)

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#### **PUBLICATIONS RELATED TO THIS REPORT**

The original clinical practice guideline from 2010 was published in the peer-reviewed journal *Clinical Oncology*:

1. Wright F, Spithoff K, Easson A, Murray C, Toye J, McCready D, et al. Primary excision margins and sentinel lymph node biopsy in clinically node-negative melanoma of the trunk or extremities. *Clin Oncol.* 2011;23:572-578.

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# Primary Excision Margins and Sentinel Lymph Node Biopsy in Cutaneous Melanoma

## Recommendations

*This is a quick reference guide and provides the guideline recommendations only. For key evidence associated with each recommendation, the systematic review, and the guideline development process, see the Full Report.*

### GUIDELINE OBJECTIVES

To provide guidance on the optimal surgical excision margins and use of sentinel lymph node biopsy (SLNB) in adults diagnosed with cutaneous melanoma located on the trunk, extremities, and head and neck.

### TARGET POPULATION

These recommendations apply to adults (>18 years) diagnosed with truncal, extremity, or head and neck non-metastatic cutaneous melanoma.

### INTENDED USERS

Intended users of this guideline include general surgeons, otolaryngologists, head and neck surgeons, surgical oncologists, dermatologists, and plastic surgeons that provide care for patients with melanoma. Additionally, all clinicians and healthcare providers who are involved in the management or referral of patients with cutaneous melanoma are intended users of these recommendations.

### UPDATES FROM 2010

In 2010, the Melanoma Disease Site Group developed a systematic review and clinical practice guideline to provide healthcare providers with guidance on optimal primary resection margins and the use of SLNB in patients with cutaneous melanoma located on the trunk or extremities [Evidentiary Base from 2010 Guideline]. As this guideline is now six years old and new evidence has emerged in the field, the Working Group of the Surgical Management of Melanoma Guideline Development Group developed this evidentiary base to update the recommendations of the clinical practice guideline. The following are key differences between the 2010 and current guideline:

- Recommendations specific to patients with head and neck melanoma have been added. This patient population was not included in the 2010 Guideline.
- Surgical margins for in situ melanomas of the trunk and extremities have been increased from 5 mm to a range of 5 mm to 1 cm.
- Surgical margins for pT2 melanomas of the trunk and extremities remain at 1 to 2 cm but a 2 cm margin, when possible, is suggested.
- Surgical margins for pT3 melanomas of the trunk and extremities have been increased from a range of 1 to 2 cm to 2 cm.
- The recommendations for SLNB have been significantly updated based on new evidence.

It should be noted that the studies used to inform the 2010 recommendations are included in two systematic reviews [1,2] and, therefore, have been included in this 2017 update of the 2010 Guideline.

**RECOMMENDATIONS**

**Recommendation 1 - Surgical Margins for Melanoma located on the Trunk and Extremities**

After initial excision or biopsy for melanoma located on the trunk and extremities, the radial excision margins, measured clinically from the edge of the melanoma or biopsy scar, should be:

Melanoma Depth/Thickness	Margin
pTis melanoma in situ	5 mm-1 cm
pT1 melanoma ≤1.0 mm	1 cm
pT2 melanoma 1.01-2.0 mm	1-2 cm
pT3 melanoma 2.01-4.0 mm	2 cm
pT4 melanoma >4.01 mm	2 cm

***Qualifying Statements for Recommendation 1***

- For melanoma in situ, there are no randomized controlled trials evaluating appropriate surgical margins. In a single prospective study of pathologic margins for melanoma in situ, 86% of patients had clear pathologic margins with a 6 mm-wide excision margin and 98.9% of melanoma in situ were completely excised with a 9 mm surgical margin [3]. Consequently, some patients may require wider surgical margins of 1 cm to achieve clear pathologic margins.
- Where possible, for pT2 lesions, it may be desirable to take a wider margin (2 cm) for these tumours depending on tumour site and surgeon/patient preference, because evidence concerning optimal excision margins is unclear.

**Recommendation 2 - Surgical Margins for Cutaneous Melanoma located on the Head and Neck**

After initial excision or biopsy for cutaneous melanoma located on the head and neck, the radial excision margins, measured clinically from the edge of the melanoma or biopsy scar, should be:

Melanoma Depth/Thickness	Margin
pTis melanoma in situ	5 mm-1 cm
pT1 melanoma ≤1.0 mm	1 cm
pT2 melanoma 1.01-2.0 mm	1-2 cm
pT3 melanoma 2.01-4.0 mm	2 cm
pT4 melanoma >4.01 mm	2 cm

***Qualifying Statements for Recommendation 2***

- For melanoma in situ, margin-controlled excision may provide tissue sparing and improved tumour clearance in challenging locations such as near the eye, nose, lips, and ears.
  - In this context, margin-controlled excision refers to assessment of margins prior to reconstruction so that surgeons may perform further resection until clear margins are achieved. This can be achieved via Mohs surgery or other forms of en face margin control prior to reconstruction; however, the superiority of one technique over the other is outside of the scope of this Guideline.
- For pT2 melanomas, where possible, it may be desirable to take a wider surgical margin (2 cm) for these tumours depending on tumour site and surgeon/patient preference, because evidence concerning optimal excision margins is unclear.

- It is recognized that wide margins may not always be possible based on the location of melanoma in relation to facial structures. When possible, wide margins should be employed; however, they may be difficult to achieve when melanoma is located on the eyelid, nose, lip, or ear.

**Recommendation 3 - SLNB for Melanoma located on the Trunk and Extremities**

Patients with a clinically node negative, stage I or II melanoma, >1.0 mm in thickness and located on the trunk and extremities should be given the opportunity to discuss SLNB to provide staging and prognostic information.

Melanoma Depth/Thickness	Use of SLNB
pTis melanoma in situ	Not recommended
pT1 melanoma $\leq 1.0$ mm	If melanoma is $\geq 0.75$ mm, has a Clark level IV/V, high mitotic rate ( $\geq 1$ mitosis/mm <sup>2</sup> ), ulceration, or microsattellites, physicians should discuss SLNB with these patients. If the results of SLNB indicate these patients have melanoma metastases in their sentinel node, they may benefit from adjuvant therapy and/or entry into adjuvant clinical trials and therefore may have an improved melanoma-specific survival (MSS).
pT2 melanoma 1.01-2.0 mm and pT3 melanoma 2.01-4.0 mm	SLNB is recommended for these patients to provide locoregional control and to identify patients who may benefit from adjuvant therapy and/or entry into adjuvant clinical trials. SLNB does provide an MSS benefit if the sentinel node contains melanoma metastases.
pT4 melanoma >4.01 mm	Physicians should discuss SLNB with these patients and to identify patients who may benefit from adjuvant therapy and/or entry into adjuvant clinical trials. SLNB will provide prognostic information and may provide locoregional control but not MSS benefit.

**Qualifying Statements for Recommendation 3**

- SLNB should be performed only following discussion of the options with the patient, in a high-volume unit (>50 cases) with access to appropriate surgical, nuclear medicine, and pathology services.
  - The false-negative rate of SLNB is lowest when >50 cases have been performed at the institution [4].
  - A double dye technique with Tc99 and blue dye (isosulfan or patent blue) increases the identification rate of the sentinel lymph nodes (SLNs) [5]
- For patients with intermediate-thickness melanomas diagnosed with nodal metastases on pathology of the sentinel node(s), there is a 10-year MSS benefit for SLNB; however, overall survival was not reported.
- SLNB should be discussed with patients to identify those eligible for adjuvant therapy and for enrollment into clinical trials.
- Ideally, for best accuracy, SLNB is performed at the same time as the wide local excision of the primary melanoma. SLNB is less reliable or may fail when performed as a separate operation for a patient having already had their wide local excision and repair with any flap (with the exception of an advancement flap) or skin graft.

<b>Recommendation 4 - SLNB for Cutaneous Melanoma located on the Head and Neck</b>	
<p>Patients with a clinically node-negative, stage I or II cutaneous melanoma &gt;1.0 mm in thickness and located on the head and neck should be given the opportunity to discuss SLNB to provide staging and prognostic information.</p>	
Melanoma Depth/Thickness	Use of SLNB
pTis melanoma in situ	Not recommended
pT1 melanoma ≤1.0 mm	If melanoma is ≥0.75 mm thickness, has a Clark level IV/V, high mitotic rate (≥1 mitosis/mm <sup>2</sup> ), ulceration, or microsatellites, physicians should discuss SLNB with these patients. If the results of SLNB indicate these patients have melanoma metastases in their sentinel node they may benefit from adjuvant therapy and/or entry into adjuvant clinical trials and therefore may have an improved MSS.
pT2 melanoma 1.01-2.0 mm and pT3 melanoma 2.01-4.0 mm	SLNB is recommended for these patients to provide locoregional control and to identify patients who may benefit from adjuvant therapy and/or entry into adjuvant clinical trials. SLNB does provide a MSS benefit if the sentinel node contains melanoma metastases.
pT4 melanoma >4.01 mm	Physicians should discuss SLNB with these patients. SLNB will provide prognostic information and may provide locoregional control but not MSS benefit.
<b>Qualifying Statements for Recommendation 4</b>	
<ul style="list-style-type: none"> <li>• SLNB should be performed only following discussion of the options with the patient, in a unit with access to appropriate surgical, nuclear medicine, and pathology services. <ul style="list-style-type: none"> <li>○ The false-negative rate of SLNB is lowest when &gt;50 cases have been performed at an institution [4].</li> <li>○ A double dye technique with Tc99 and blue dye (isosulfan or patent blue) increases the identification rate of the SLNs [5]</li> </ul> </li> <li>• SLNB should be discussed with patients to identify those eligible for adjuvant therapy and for enrollment into clinical trials.</li> <li>• Ideally, for greatest accuracy, SLNB should be performed at the same time as the wide local excision of the primary melanoma. SLNB is less reliable or may fail when performed as a separate operation for a patient having already had a wide local excision and repair with any flap (with the exception of an advancement flap) or skin graft.</li> </ul>	

**Technical Considerations**

These considerations have been transcribed from the original 2010 guideline and any changes have been italicized. As such, the technical considerations are based on evidence identified in the original systematic review [Evidentiary Base from 2010 Guideline].

***Excision Margins***

- The depth of the excision should be down to, *but not including*, the fascia.
- Margins (e.g., 1 cm or 2 cm) should be included in the surgical operating room *report and are clinically measured with a ruler at the time of surgery from the visible edge of the melanoma or previous biopsy scar.*
- Standard synoptic pathology reporting should be used *for both the primary melanoma and the sentinel node biopsy.*

- Excision margins should be 1 to 2 cm where possible but may involve amputation depending on the anatomical location of the lesion (e.g., fingers and toes). For more complex areas, such as fingers and toes, or where the primary melanoma involves anatomic areas not amenable to simple wide excision, multidisciplinary input should be sought.
- *Total radial margin excision may include margins from biopsy as well as wide local excision, as clinically appropriate.*

#### ***Sentinel Lymph Node Biopsy***

- Lymphoscintigraphy after *intra*dermal injection of radioactive tracer is mandatory to identify SLNs.
- Either patent blue or isosulfan blue dye is recommended *in addition to the radioactive tracer*.
- SLNB assessment should include the use of immunohistochemistry and hematoxylin & eosin staining.
- *Size of melanoma metastases should be noted in the pathology report as should extranodal extension for each positive node.*

#### **FURTHER QUALIFYING STATEMENTS**

- Physicians should discuss the feasibility of enrollment into clinical trials with all patients.

#### **IMPLEMENTATION CONSIDERATIONS**

These recommendations are best implemented in the context of a multidisciplinary team and with involvement of a pathologist with expertise in dermatopathology.