Melanoma Treatment Guidelines 2021

Diagnosis

Biopsy for suspicious pigmented skin lesion

Evidence based recommendations

- The optimal biopsy approach for a suspicious pigmented lesion is complete excision with a 2mm peripheral clinical margin, and deep into the upper subcutis.
- Partial biopsies are not fully representative of the lesion and need to be interpreted with caution, and in light of the clinical findings, to minimise incorrect false negative diagnoses and under-staging.
- In carefully selected clinical circumstances (such as large, flat lesions, large facial or acral lesions or where the suspicion of melanoma is low) and in the hands of experienced clinicians, partial incisional, punch or shave biopsies may be appropriate.

Practice points

- It is advisable to discuss unexpected pathology results with the reporting pathologist.
- Punch biopsy should not be utilised for the routine diagnosis of suspected melanoma because this technique is associated with high rates of histopathological incorrect false negative diagnosis.
- Where a punch biopsy has been used for the diagnosis of a suspected BCC or SCC, and the diagnosis has been found to be melanocytic, then consideration should be given to excision of the entire lesion.
- The use of deep shave excision (saucerisation) should be limited to flat lesions to preserve prognostic features and optimise accurate planning of therapy.
- Consider sending a photograph of the lesion, taken before biopsy, to the pathologist with the request form, as this may assist definitive diagnosis. Also, consider using 'tissue marking ink' with a 25G needle to highlight suspicious parts of the excision biopsy, to direct the pathologist's attention.

Staging and treatment

The process of staging most melanomas that are diagnosed in primary care is simple and straightforward, as the large majority of such lesions are either in situ melanoma or thin invasive melanoma.

Please refer to the melanoma staging table and flow chart.

Melanoma in situ (MIS)

MIS is Stage 0 and does not need sentinel lymph node biopsy (SLNB).

MIS can be managed in primary care with wide local excision of 5-10mm margins (depending on location, but with a preference for 10mm).

Invasive melanoma

If the **Breslow thickness is <1mm with no ulceration and no mitoses**, there is no need to consider SLNB and wide local excision can proceed in primary care, with 10mm margin.

If the **Breslow thickness is >1mm or is >0.8mm with ulceration or mitoses**, SLNB discussion is necessary.

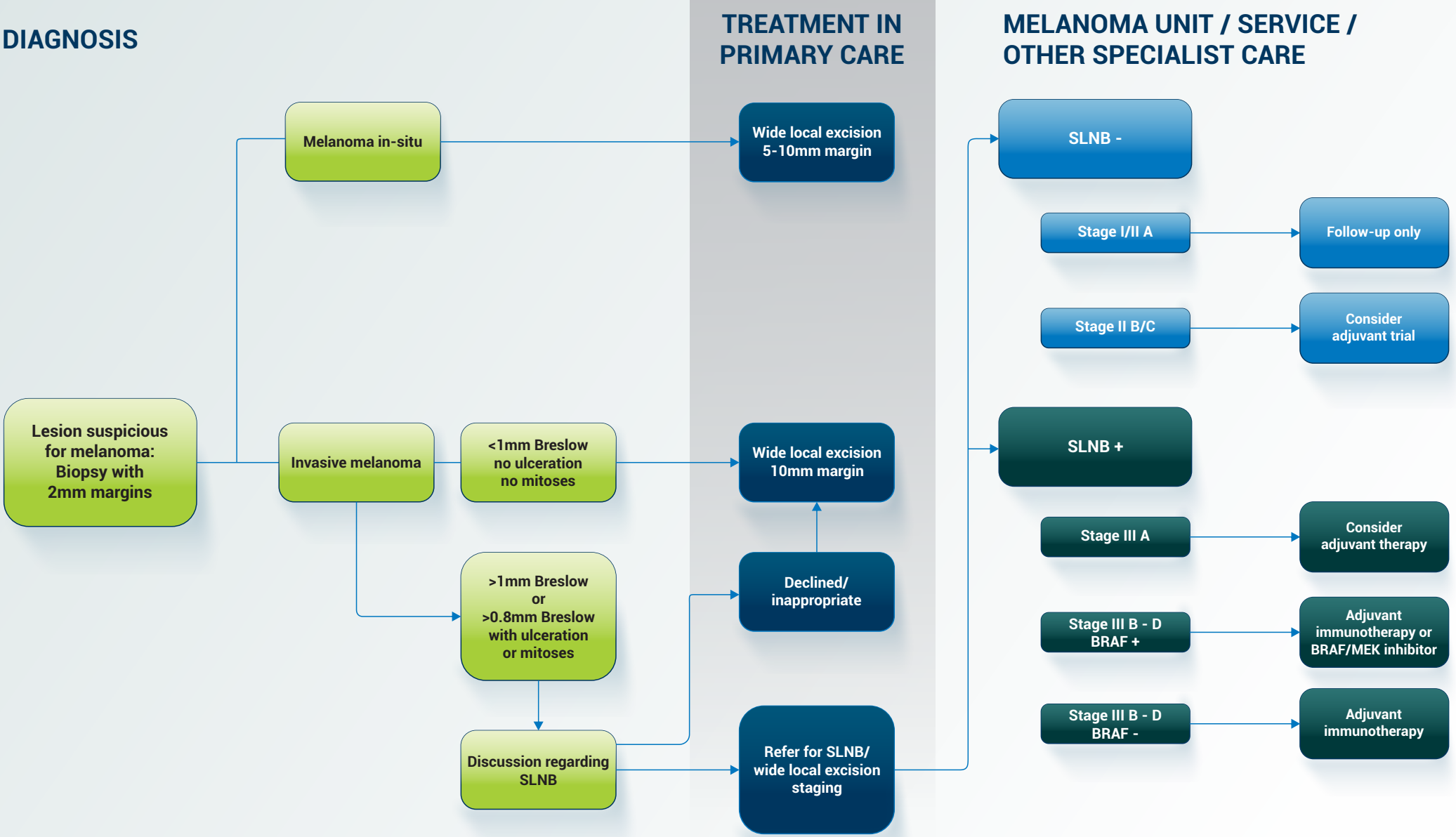
SLNB provides useful prognostic information and (very importantly) provides an access point to adjuvant therapy: all patients with positive SLNB are considered for adjuvant therapy.

If SLNB is declined or considered inappropriate (for example, very elderly or significant comorbidity, etc), wide local excision may proceed.

In most other cases, referral for SLNB and wide local excision is appropriate, and will be followed by adjuvant therapy.

Stage 1 and Stage 2 are **invasive melanomas** but with negative sentinel lymph node biopsy (SLNB). Further differentiation within Stage 1 and Stage 2 is based on both thickness and presence or absence of ulceration.

Stage 3 and Stage 4 invasive melanomas refer to SLNB positive and more distant metastases, and such staging requires hospital evaluation.



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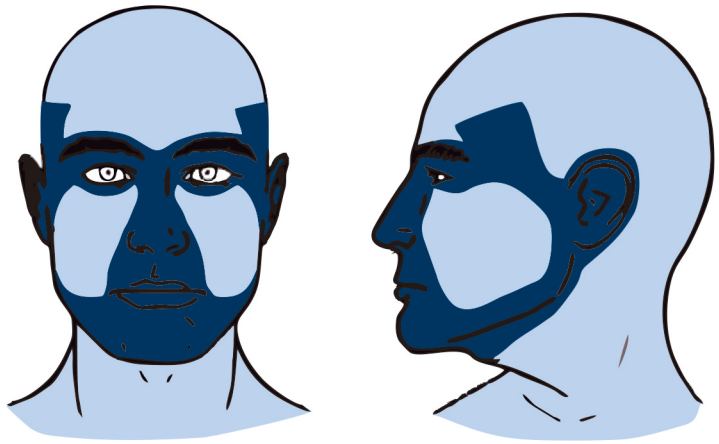
MELANOMA STAGING		
Stage	**Classification**	**5-year survival**
Stage 0	Tis: Melanoma in situ	>98%
Stage I (A/B)	T1a: <0.8 mm and nonulcerated	97–92%
	T1b: ≥0.8 mm or <0.8 mm with ulceration	
	T2a: >1.0–2.0 mm without ulceration	
Stage II (A, B, C)	T2b: >1.0–2.0 mm with ulceration	81–53%
	T3a: >2.0–4.0 mm without ulceration	
	T3b: >2.0–4.0 mm with ulceration	
	T4a: >4.0 mm without ulceration	
	T4b: >4.0 mm with ulceration	
Stage III (A, B, C, D)	N1a: 1 clinically occult (in SLN biopsy)	78–40%
	N1b: 1 clinically detected	
	N1c: presence of in-transit, satellite, and/or microsatellite mets	
	N2a: 2–3 clinically occult (in SLN biopsy)	
	N2b: 2–3, at least 1 clinically detected	
	N2c: 1 clinically occult or detected, with in-transit, satellite, and/or microsatellite mets	
	N3a: 4 or more clinically occult (in SLN biopsy)	
	N3b: 4 or more, at least 1 of which clinically detected, or presence of any number of matted nodes	
	N3c: 2 or more clinically occult or clinically detected with in-transit, satellite, and/or microsatellite mets	
Stage IV	Distant metastasis: location and LDH levels define sub-stage	20–15%

Adapted from Gershenwald JE et al. AJCC cancer staging manual. 8th ed. Amin MB, editors. Chicago, IL: American Joint Committee on Cancer; 2017. p. 563.

Basal cell carcinoma (BCC) treatment algorithm

Categorise as low risk or high risk BCC (histology, body site, other factors):

	Low risk	High risk[a]
Clinical criteria		
Location and size	Area L[b] ≤ 20 mm (maximum clinical diameter) Area M[c] ≤ 10 mm (maximum clinical diameter)	Area L[b] > 20 mm (maximum clinical diameter) Area M[c] > 10 mm (maximum clinical diameter) Area H[d]
Borders	Well defined	Poorly defined
Primary vs recurrent	Primary	Recurrent
Immunosuppression	No	Yes
Site of prior radiotherapy	No	Yes
Pathological criteria BCC and stage		
Growth pattern	Nodular or superficial	Infiltrative (infiltrating, morphoeic, micronodular)
Differentiation: basosquamous	Absent	Present (with or without lymphovascular invasion)
Level of invasion	Dermis, subcutaneous fat	Beyond subcutaneous fat
Depth (thickness)	≤ 6 mm	> 6 mm
Perineural invasion[e]	Absent	Present
Pathological TNM stage	pT1 ≤ 20 mm (maximum diameter)	pT2 > 20 mm but ≤ 40 mm (maximum diameter) pT3 > 40 mm (maximum diameter), or upstaged[f] pT1 or pT2, or minor bone invasion pT4 major bone invasion
Margins		
Histological margins	Not involved (≥ 1 mm)	Involved (0 mm) or histologically close (< I mm)



TNM, Tumour-Nodes-Metastasis. [a]One or more criteria equals high risk, unless stated differently in the summary of the recommendations, or in an explanatory note. [b]Area L = trunk and extremities **but excluding** hands, nail units, genitals, pretibia, ankles and feet. [c]Area M (see Figure 1) = cheeks, forehead, scalp, neck and pretibia. [d]Area H (see Figure 1) = 'mask areas' of face [central face, eyebrows, periorbital, nose, lips (cutaneous and vermilion), chin, mandible, preauricular, postauricular, temple, ears]; genital areas; hands, nail units, ankles and feet, but **excluding the eyelid**. For tumours < 6 mm in size without other high-risk features, standard surgical excision may be considered if a > 4 mm clinical surgical margin can be obtained without significant anatomical or functional distortions. [e]A named nerve or a diameter > 0.I mm or beyond the dermis. [f]T1 and T2 can be upstaged to T3 by the presence of one or more high-risk clinical or pathological factors comprising specifically defined perineural invasion or deep invasion representing either a tumour thickness or depth > 6 mm and/or invasion beyond or further than the subcutaneous fat.

Treatment

- Surgical excision offered as first line treatment for all low-risk BCC, 4mm margins, clear deep plane
- Surgical excision offered – with immediate closure - as first line treatment for all high-risk BCC with well-defined tumour margins, >=5mm margins and clear deep plane
- Surgical excision offered – with delayed closure - as first line treatment for all high-risk BCC with poorly-defined tumour margins, >=5mm margins and clear deep plane
- Consider Mohs if high-risk plus 1 other high-risk factor
- Excision or radiotherapy for advanced BCC (consider Mohs)
- Radiotherapy as an option in >60y if unsuitable for / declined excision
- Topical imiquimod, 5FU, cryosurgery, PDT only for low-risk BCC who decline surgery

Following primary treatment

- Re-excision for involved margins
- Close margin (<1mm) – offer excision, radiotherapy or monitor
- Follow up 6-12 monthly

Squamous cell carcinoma (SCC) treatment algorithm

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Categorise the tumour / patient risk status

	Low risk	High risk	Very high risk
Tumour factors	• Tumour diameter <+20mm (=pT1) • Tumour thickness <=4mm • Invasion into dermis • No perineural invasion • Well-differentiated or moderately differentiated • No lymphovascular invasion **ALL ABOVE FACTORS MUST APPLY**	• Diameter >20-40mm (=pT2) • Thickness >4mm-6mm • Invasion into subcut fat • Perineural invasion – dermal only; nerve diameter <0.1mm • Poorly differentiated • Lymphovascular invasion • Ear or lip **ANY SINGLE FACTOR DENOTES HIGH RISK**	• Diameter >40mm (=pT3) • Thickness >6mm • Invasion beyond subcut fat, any bone • Perineural invasion in named nerve; nerve >=0.1mm; or nerve beyond dermis • High grade subtype (adenosquamous, desmoplastic, spindle, sarcomatoid, metaplastic) • In transit mets **ANY SINGLE FACTOR DENOTES VERY HIGH RISK**
Margin status	Clear pathology margins in all dimensions (>=1mm)	1 or more involved or close (<1mm) margin in a pT1 tumour; close margin in a pT2 tumour	1 or more involved or close (<1mm) margin in a high-risk tumour
Patient factors	Immune-competent	Iatrogenic immunosuppression or biological therapies; frailty or comorbidities; HIV on HAART	As for high risk, especially solid organ transplant, heamatol malignancy, other significant immunosup
Follow up	6m, 12m then at least annual, full skin check	Every 4m for 12m, and every 6m thereafter	Every 4m for 24m and every 6m thereafter

Treatment

Surgery

- Standard surgical excision is the first line option for resectable SCC
- Tumour margins (bright light, magnification, dermoscopy) are >=4mm for low risk, >=6mm for high risk and >=10mm for very high-risk SCC
- Deep margins are to the next clear surgical plane (including galea on scalp), and may require inclusion of tissue below skin and fat
- Ensure 1mm histological clearance for all margins
- If margins are clear-but-close (<1mm) consider re-excision, or observation if immunocompetent and low-risk tumour
- Involved margins, or clear-but-close margins in high-risk patients may require re-excision with delayed reconstruction, Mohs surgery, or radiotherapy
- Consider Mohs surgery if high-risk and challenging surgical location

Radiotherapy / Perineural invasion

- Radiotherapy (primary) is an option in selected patients when surgery is not feasible or is especially challenging
- Radiotherapy (adjuvant) considered in clear-but-close, and in clear excision in very high-risk SCC, and involved margins with further surgery especially challenging
- Radiotherapy (adjuvant) when risk of local recurrence is high:
- Perineural invasion (multifocal, named nerve and/or diameter of nerve > 0.1 mm, below the dermis)
- Recurrent disease
- Immunocompromised
- Adjuvant radiotherapy is NOT indicated for people with completely excised T1 or T2 SCC and with microscopic, dermal-only, nerve diameter < 0.1 mm perineural invasion
- Symptomatic (or radiological) perineural invasion requires specialist referral (for aggressive surgical excision of the affected nerve)

Curettage and cautery

- Curettage and cautery is an option, with curative intent, in immunocompetent people with small (< 1 cm), well-defined, nonrecurrent, clinically low-risk SCC
- Review pathology carefully to ensure no high-risk factors

Imaging and specialist referral

- MRI or high-resolution ultrasound is indicated when clinical evidence of lymph node involvement, symptomatic perineural invasion, or very high-risk lesions
- Specialist referral when evidence or suspicion of metastasis, consideration of regional dissection, immunotherapy and chemotherapy

Follow up

- Low risk – 6m, 12m then at least annual
- High risk - 4 monthly for 12m, then 6 monthly ongoing
- Very high risk – 4 monthly for 24m, then 6 monthly ongoing