





NICE 2022 guidelines on the management of melanoma: Update and implications



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Summary Aims: In July 2022, NICE updated the guidelines on the management of melanoma
by lowering the number of follow-up appointments and sentinel lymph node biopsy (SLNB) but
increasing the number of scans. This study aims to evaluate the implications of executing the
new guidelines in terms of cost-effectiveness and personnel.
Methods: All patients newly diagnosed with melanoma in 2019 at a regional skin cancer spe-
cialist center were reviewed. Data were analyzed for their journey on an idealized pathway
modeled over a 5-year follow-up period when adhering to both the previous and new guidelines.
Differences in the management of melanoma were elucidated by comparing these changes. The
cost was quantified on a perpatient basis and the financial implication on each department was
considered.
Results: One hundred and ten patients were diagnosed with melanoma in 2019, stages I-III. The
changes ease the burden on plastic surgery and dermatology; however, increased pressure is
faced by radiologists and histopathologists. An overall cost benefit of £141.85 perpatient was
calculated, resulting in a decrease of 1.22 hospital visits on average and an increase in the time
spent there (19.55 min). The additional expenses of implementing the new guidelines due to
the added BRAF tests, CT, and ultrasound scans are outweighed by savings from the reduction in
follow-up appointments and SLNB.
Conclusion: The focus has shifted to less invasive procedures for lower melanoma stages and
fewer follow-up appointments, at the expense of more genetic testing and imaging. This paper

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serves as a useful baseline for other centers to plan their service provision and resource allocation to adhere to the updated guidelines.

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There are nearly 17,000 new melanoma cases in the UK per vear (2016-2018). It is the fifth most common cancer in the UK and is on the rise, projected to increase to 32 cases per 100,000 people by 2035.¹ Many developed Western countries are seeing a rise in the number of cutaneous melanoma cases since it mainly occurs in pale-skinned people who expose themselves to intense sunlight. Longer, sunnier summers in the Northern Hemisphere due to climate change and a growing appetite for sunny holiday destinations are contributing to this, which has increased the workload for melanoma services.² The diagnosis, staging, treatment, surveillance, and follow-up of any cancer, including melanoma, is a resource-intensive pathway requiring robust clinical guidelines to maximize cost-effectiveness. Patients receive a melanoma diagnosis following a diagnostic excisional biopsy, which dictates histological staging. Depending on the stage of melanoma and other high-risk tumor features, a series of investigations such as sentinel lymph node biopsy (SLNB) and gene testing may be indicated, which could extend treatment to adjuvant systemic anti-cancer therapy (SACT), alongside surgery (Figure 1).

New research into the advances of treatment modalities has prompted an update to the National Institute of Health and Care Excellence's (NICE) guidelines in July 2022. These guidelines aim to reduce the variation in clinical practice across the UK; including disparity with regard to the use of dermoscopy, photography, access to SLNB, and follow-up imaging.³ However, implementation of these guidelines in individual hospitals could cause problems due to changes in workload between departments and financial implications, particularly for patients presenting at stages I-III. Guidelines for stage IV patients on adjuvant therapy (such as immunotherapy or targeted therapy) are far less prescriptive, and therefore their management has not been impacted by the new guidelines.

Key changes to the guidelines for stages I-III that are likely to have an impact are:

- 1. Clinic follow-up regime
- 2. Reduction in requirement for SLNB
- 3. Increase in the use of ultrasound of nodal drainage basin
- 4. Change in indication and frequency of computer tomography (CT) scan follow-up



Figure 1 Melanoma patient care and management pathway.

5. Use of magnetic resonance imaging (MRI) instead of CT in pregnant or young women to reduce radiation burden.

This paper aims to assess the workload and cost impacts of the 2022 NICE guidelines at the University Hospitals of Leicester NHS Trust (UHL), by taking an annual cohort of patients diagnosed with melanoma and modeling their journey for both the previous and new guidelines. This allows comparison of the workload experienced by different departments involved in the melanoma patients, financial implications, and the effects it has on the patients diagnosed with melanoma. The paper is intended to serve as a tool for other organizations to use for resource allocation to melanoma services whilst attempting to adhere to the new guidelines.

Methods

Study design and participants

This study was conducted in a regional skin cancer specialist center with a retrospective element that reviewed all patients who were diagnosed with melanoma between 1st January 2019 and 31st December 2019. All patients were stratified by melanoma stage according to the 8th edition of the American Joint Committee on Cancer (AJCC) staging system. Patients who would be considered for SLNB were included in the study (stages I to III), those not appropriately staged were excluded.

Histopathology results of stage IB were manually screened via the UHL's electronic patient records system, Integrated Clinical Environment (ICE, Clinisys Winpath, UK) in order to determine high-risk features and Breslow thickness (BT).

The cost of appointments, scans, and screening procedures was acquired through the UHL financial department using the appropriate clinical codes.

Timing for follow-up appointments and scans was acquired through the UHL's clinic booking system.

2019 was taken as the baseline for the evaluation due to changes seen in clinical practice and workload in the following years because of the COVID-19 pandemic.

The data from the retrospective study were analyzed for their journey on idealized pathways modeled over a follow-up period of 5 years for both the previous guidelines and the 2022 melanoma NICE guidelines. The number of follow-up appointments and investigations of our 2019 patient cohort was compared to the number of follow-up appointments and investigations recommended by the July 2022 guideline.⁴

Data analysis

An analysis was conducted for each specialty to inform the trust about the changes required with regard to resource allocation.

The time implications of the new guidelines were calculated for both patients and clinicians. The time for each appointment, CT scan, ultrasound scan, and the time reguired to interpret these scans were collected to calculate the total change in the number of minutes/hours for each of these components as well as for the patient and clinician. The data were analyzed using Microsoft Excel (Microsoft Office 365, USA).

Results

Changes to follow-up and costs

Overall, 121 patients were diagnosed with melanoma at UHL in 2019. Eleven stage 4 patients were excluded, leaving 110 stage I-III patients in our study group.

Figure 2 demonstrates the distribution of this cohort by disease stage, as well as showing the 11 stage IV patients not included in further calculations:

The costs of services impacted are as follows: a follow-up appointment is £140.94, a staging CT scan is £428.83; an ultrasound of the single lymph node basin is £234.36, SLNB is £2088 and BRAF testing is £97.

Figure 3 shows differences in anticipated clinic appointments, CT, and ultrasound scans over a 5-year followup period based on previous and new NICE guidelines. Table 1 gives the cost implications of these changes. This shows there would be a reduction of 483 follow-up clinic appointments across melanoma stages I-III. There would be an increase of 34 extra CT scans recommended and an increase of 315 ultrasound scans if the patient cohort at UHL in 2019 were followed up according to the new 2022 guidelines. SLNB demand has fallen due to more stringent criteria for offering SLNB being imposed, but BRAF genetic testing has increased in demand (Table 1).

In the new guideline, 15 patients would be eligible for BRAF testing and 18 patients would no longer be eligible to undergo SLNB, reducing the overall cost of providing these two services by £35,935 (the reduction in SLNB accounting for the majority of this saving).

Implementing the new guidelines represents a decrease in cost of £15,602.99, largely due to the extra costs of BRAF tests, ultrasound scans, and CT scans being less costly than the savings due to the reduction in follow-up appointments and SLNB load (Table 1, Figure 4). Per patient, this represents a decrease in cost of £141.85 (Table 1).



Figure 2 Distribution of 2019 UHL melanoma patients by disease stage.



Figure 3 Number of clinic appointments, CT scans, and ultrasound scans for patients presenting in 2019 and the predicted figures for the patients in 2022 following the new NICE guidelines.

Table 1 Summary of changes to demand and	Table 1	Summarv o	f changes	to demand	and cost.
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	2019 Guid	elines	2022 Gui	delines	Difference	2
	Number	Cost (£)	Number	Cost (£)	Number	Cost (£)
Clinic appointments	1208	170,255.52	725	102,181.5	-483	-(68,071.61)
SLNB	24	50,112.00	6	12,528.00	-18	-(37,584.00)
BRAF genetic tests	23	2231.00	40	3880.00	17	1649.00
Ultrasound	0	0.00	315	73,823.40	315	73,823.40
CE-CT scans (whole body + brain)	176	75,474.08	210	90,054.3	34	14,580.22
Change in total imaging costs						88,403.62
Change in total costs						-(15,602.99)

Impact on patients and staff

Ultrasound and CT scans are both allocated 20 min for patients. Many sonographers report the ultrasound scan within the 20-minute window, whereas reporting on a whole-body CT scan as is used for melanoma follow-up, takes an average of 30 min. Although, the standardized reporting time for ultrasound is 12.5, and 45 min for CT scans.⁵ Follow-up appointments are allocated 10 min (Table 2). The number of patient visits to the hospital for appointments and scans will decrease by 134, which results in a decrease of 1.22 visits to the hospital per patient.

Discussion

Department-stratified demand changes

The changes to the NICE guidelines generally favor a higher imaging demand for radiologists and greater demand on



Figure 4 Total cost of appointments, CT scans, and ultrasound scans, BRAF genetic tests, and SLNB in 2019 and the predicted figures in 2022 following the new NICE guidelines.

Cumulative time	2019 UHL (hours)	2022 Guideline (hours)	Difference (hours)
Total appointment time	201.3	120.8	-80.5
Total scanning time	58.7	175	+116.3
Time spent by radiology interpreting scans	88	105	+17.0
Total time spent in hospital for patients	260	295.8	+35.8
Time per-patient	2019 UHL (hours)	2022 Guideline (hours)	Difference (hours)
Total appointment time demand per patient	1.8	1.1	-0.7
Total scanning time per patient	0.5	1.6	+1.1
Time spent by radiology interpreting scans per patient	0.8	1.0	+0.2
Time spent in hospital per patient	2.4	2.7	+0.3

histopathology departments for genetic testing, but lower demands on plastic surgery and dermatology services as a result of fewer appointments and reduced numbers of SLNB.

BRAF testing is now being considered at earlier stages, such as IIA and IIB according to the newer guidelines. As per evidence, stage IIA-IIC melanoma patients have comparable mortality rates to stage IIIA-IIIB, so the 2022 guidelines advise BRAF at diagnosis. This indicates that if there is disease progression, treatment can be started immediately, avoiding the delay associated with retrieving the previous samples for BRAF testing at a later stage. Following the new guidelines, SLNB will not be offered to all melanoma patients with a Breslow thickness of 0.8-1.0 mm as is currently done at UHL. Evidence reviews for the use of sentinel lymph node biopsy in people with melanoma suggest that the group of patients with a pT1b melanoma of 0.8-1.0 mm Breslow thickness is unsustainably large, the prevalence of a positive result is still quite small and the procedure is costly and invasive. The new guidelines suggest that SLNB should only be offered to stage IB patients with lesions of 0.8-1.0 mm Breslow thickness with at least one of the concomitant high-risk features (ulceration, lymphovascular invasion or a mitotic index of

2 or more) too, which decreases the burden on plastic surgery services. A recent paper⁶ found that stage 1b melanoma patients had a positive SLNB in only 8% of cases, but the cost of this procedure increases overall treatment costs fourfold. There also needs to be the potential consideration of SLNB surgical colleagues redirecting their resources to other procedures, potentially improving other aspects of the surgical services; theater time and personnel are likely to be redirected rather than 'lost'.

The imaging demand has increased due to considering ultrasound scan of the draining nodal bed when SLNB was considered but not done in stages IB-III disease. CT scan numbers also increase, but by significantly less than ultrasound.

Where SLNB is no longer performed, ultrasound is used to assess the drainage bed and has the advantage of being cheaper than other forms of cross-sectional imaging and involving no ionizing radiation, unlike CT scanning. However, ultrasound is also added to follow-up regimes where CT scanning has traditionally been the sole investigation. This is due to the developing of evidence that new ultrasound morphology criteria have significantly increased the sensitivity of this technique. This and the ease of adding fine needle aspiration cytology (FNAC) at the time of testing has increased its use in melanoma, breast, and thyroid cancers. However, despite the potential superior diagnostic performance, it is unclear whether ultrasound follow-up would have any therapeutic or outcome impact.⁷

A problem with introducing ultrasound with new morphological diagnostic criteria and a straight-to-FNAC approach is that it requires a specific skill set that will not be available on routine ultrasound lists, increasing the cost.

The greater CT demand is somewhat concerning due to the greater radiation dose, particularly for early-stage disease in young patients. Melanoma occurs relatively frequently in younger age groups compared to other cancers. It has an average incidence rate of 11.8 per 100,000 in women and 6.1 per 100,000 in men between the ages of 20 and 39.¹ However, the specificity and sensitivity of CT scanning for surveillance are unrivaled for the whole body, and it remains a key component of gold-standard follow-up, caveated by NICE recommending MRI instead for CTconstrained patients such as pregnant women and patients aged 0-24 or for patients with suspected brain metastases.

Furthermore, increased imaging use especially CT leads to a higher rate of incidental findings being diagnosed. Incidental pulmonary embolisms (PE) are reported in 1%-5% of chest CTs.⁸ Treatment of non-symptomatic PEs currently involves anticoagulation, which carries a risk of major bleeding of 7.2 per 100 patient years, particularly in high-risk patients such as those with cancer.⁹ Survival rates of patients with untreated non-symptomatic PEs are similar to agematched patients who are not treated though mixed results are found in patients with active cancer.^{10,11} The prevalence of malignant incidentalomas has been reported in 5% of brain scans and 10%–20% of other solid organs such as prostate and colon.¹² As a result, we might see a higher level of anxiety and over-investigation in our melanoma patient cohort with incident findings from their routine CT or MRI scans, especially in the lower-stage melanoma patients who require less frequent scans. In higher-stage patients the frequency of scans can allow for monitoring of incidental findings without invasive investigation unless they show progressive high-risk features to indicate malignancy.

For an average melanoma patient, there are marginally fewer hospital visits on average (-1.22) with the new guidelines, but slightly greater time spent in hospital overall (19.55 min), but neither represents large changes. For the dermatology and plastics services, the appointment time per patient has decreased by 43.9 min, and for plastic surgery there will be a 75% reduction in SLNB procedures offered with their associated time commitment, but for the radiology department there is a sizeable increase in the imaging demand of 63.45 min per patient to conduct the extra scans and 9.27 min extra per patient to interpret them. However, the standardized recommended reporting times by the Royal College of Radiologists (2019) are 12.5 min and 45 min for the ultrasound and CT scans, respectively which are greater than the values used in the calculations. This will further increase the value of the calculated time spent by the radiologists interpreting the scans.

In the current state of National Health Service (NHS) waiting lists these changes will aid the treatment of other surgical patients, speed up the process of having a wide local excision and decrease the demand for nuclear medicine. This also decreases the risk from other adjuncts used in SLNB such as the blue dye anaphylaxis risk of 6 in 1000,¹³ and radiation exposure. On the contrary, more staff will likely be needed in the radiology department to meet this demand leading to longer waiting lists if the staffing crisis is not resolved. As of September 2020, 370,000 patients in England were waiting for a CT or MRI scan,¹⁴ 23% of whom were waiting for longer than 6 weeks caused by an overall shortage of 1669 consultant radiologists.¹⁵

Additionally, higher-stage melanomas are expected to be diagnosed in the postlockdown period due to an inability to access primary care in a timely fashion, or patient anxiety about attending clinical settings, during the pandemic. This has been observed in multiple European countries.¹⁶⁻¹⁸

Waiting lists could also create confusion in treatment: UHL's current waiting list for SLNB of three months would mean that several patients would already be waiting for their surgical treatment at the point that guidance changes. In our cohort of patients, 18 out of 24 would not have been eligible for SLNB due to being deemed to have a low-risk stage 1B melanoma. Implementing the new guidance would mean that the patients that are already on the waiting list would either go through with surgery as per the old guidance or be invited to the clinic to discuss with them that this is no longer indicated. This difference in care would be trust- or clinician-dependent, which could leave them vulnerable to litigation in the future.

Greater imaging frequency will likely improve outcomes and allow therapy to be more precisely titrated, and for early-stage patients (stage IA-IIA) there will be fewer overall hospital visits as a result of the changes, reducing the burden on patients and carers. However, beyond stage IIA, the overall number of hospital visits has increased for patients to account for the extra scans.

Further quantification and the benefit of prospective studies would be required to accurately assess the impact on patients of the new guidelines in terms of outcomes.

Limitations of methodology: key assumptions

CT-alternatives

For pregnant women and children, or for other patients following multidisciplinary team discussion, MRI will be used instead of CT if available. We have assumed that no such CT- constrained patients form part of the cohort we have analyzed.

Adjuvant immunotherapy use

UHL has been using adjuvant immunotherapy since 2017 for stage III disease, and the 2022 guidelines maintain this recommendation. Follow-up length and components (appointments, CT-scans) are highly personalized for each patient, and are managed by the oncology service, not by plastic surgery and dermatology. The 2022 guidelines are flexible with their recommendation with regard to this follow-up. We have assumed with these results that all 21 stage III patients at UHL did not receive adjuvant SACT because they were ineligible, and as such, would follow a specific and defined follow-up pathway as detailed in the 2022 guidelines. This assumption is both necessary, since it would be difficult to quantify the exact burden on the oncology and radiology services of the tailored follow-up for each stage III patient on adjuvant therapy, and safe, since it is likely that there would be little difference in terms of cost effect between UHL's current practice for patients on adjuvant therapy and the new 2022 guidelines' recommendation.

Stage IV disease follow-up

The nature of stage IV melanoma warrants personalized follow-up programs, and as such, UHL has not provided specific guidance on appointment and scan schedules. There were 11 patients with stage IV disease at UHL in 2019, receiving adjuvant immunotherapy for varying amounts of time and thus with varied follow-up regimes. We have not included stage IV patients in this analysis due, firstly, to costing inaccuracies associated with this variability, and also since the care provided to stage IV patients will not change for the dermatology and plastic surgery departments between current practice and the new 2022 guideline.

Appendix A

Conclusion

The recent change in melanoma guidelines has shifted the focus onto less invasive procedures for lower melanoma stages, reducing the burden on plastic surgery and dermatology departments to meet the cancer targets. In contrast, they will create a larger workload on specific departments such as radiology and histopathology: the feasibility of this in terms of whether they would be able to meet demand should be discussed at a trust level. Overall, the average expenditure per patient has marginally decreased during the course of their melanoma treatment at the expense of slightly more time spent in the hospital to acquire the recommended scans. This, in turn, will create a need for more specialist staff to carry out and interpret these imaging investigations.

This paper serves as a useful baseline for other centers to use to plan their service provision and resource allocation to adhere to the updated NICE guidelines.

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Ethical approval

Ethical approval was not required.

Declaration of Competing Interest

The authors declare no conflict of interest.

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Guidelines.		IIIA IIIB IIIC IIID IV		No change No change No change No change Chan	1 whole-body +Consider +Consider +Consider +2 Clinician used and brain CE- 2 US 2 US whole- discretion used CTs + offer 2 US 2 US body No change P 2 US. brain of CT scans [60]	5-year 5-year (but 2-3 extra offered	1	(continued on next page)
UHL prior to 2022 and the new 2022 Guidelines.		IIB		er +Consider etic BRAF genetic testing +Consider staging with CT	Consider 2 ents whole-body rr and brain CE- CT scans + consider 2 US.	Consider 2 ents whole-body r and brain CE- CT scans + consider 2 US.	- 2 clinic ent appointments + consider 2 whole-body and brain CE- CT scans + consider 2 US.	
		ЫА		only if + Consider eslow BRAF genetic ss testing n and and eatures	: - 2 clinic ments appointments der + consider 2 US	: - 2 clinic ments appointments der + consider 2 US	: -3 clinic ments appointment der +1 US	
Summary of the changes between guidance used at		IA IB		No change + SLNB only if both Breslow thickness between 0.8 mm and 1.0 mm and other features visible.	-2 consider -2 clinic clinic appointments appoint- + consider ments then 2 US discharge	-3 clinic appointments + consider 1 US	-3 clinic appointments + consider 1 US	
nmary of the chan	vs UHL current	0 1	No change No change	No change	No change 1 clinic appoint- ment then discharge			
Table A1 Sum	Changes - 2022 vs UHL current	Stage	Managing vitamin D levels and concurrent drug treatment Assessing	Staging	Management Follow Year up 1	Year 2	Year 3	

Table A1	Table A1 (continued)										
Changes -	Changes - 2022 vs UHL current	rent									
Stage	0	IA	ΙB	IIA	IIB	IIC	IIIA	IIIB	IIIC	۵III	≥
	Year		-1 clinic	-1 clinic	- 1 clinic	-1 clinic	No change	No change No change No change	No change	+	
	4		appointments	appointments	appointment +	appointment				whole-	
					consider 1 +1 whole-body	+1 whole-body				body	
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	Year		-1 clinic	-1 clinic	- 1 clinic	-1 clinic	No change	No change	No change	+	
	ß		appointments	appointments	appointment +	appointment				whole-	
					consider 1					body	
					whole-body					and	
					and brain					brain	
					CE-CT.					CE-CT	

Table B1 Demand a	Demand and cost changes stratified by disease stage.	y disease stage.			
Stage IA Number of patients	Service	Change in service demand per	Total change in number of units	Cost per unit of	Change in total cost of service
46	Appointment	-2	-92	E140.94	E(12,966.02) E(12,966.02)
Stage IB Number of patients	Service	Change in service demand per	Total change in number of units	Cost per unit of	Change in total cost of service
24	SLNB Appointment Ultrasound	patient -0.75 -10 4	of service -18 -240 96	service £2088.00 £140.94 £234.36	E(37,584.00) E(33,824.40) E22,498.56 E(48,909.84)
Stage IIA Number of patients	Service	Change in service demand per	Total change in number of units	Cost per unit of	al cost of service
15	BRAF test Appointment Ultrasound	patient 1 5	of service 15 -135 75	service E97.00 E140.94 E234.36	E1455.00 E(19,026.23) E17,577.00 E5.78
Stage IIB Number of patients 2	Service BRAF test Staging CT Ultrasound	Change in service demand per patient 1 -4 6	Total change in number of units of service 2 -8 12	Cost per unit of service E97.00 E428.83 E140.94 E234.36	n total cost of service ()
Stage IIC Number of patients 2	Whole body + brain CE-CT Service Appointment Ultrasound Whole body + brain CE-CT	8 Change in service demand per patient 6 6	16 Total change in number of units of service -8 12 8	E428.83 Cost per unit of service E140.94 E234.36 E428.83	total cost of service
Stage IIIA Number of patients 13	Service Ultrasound	Change in service demand per patient 6	Total change in number of units of service 78	Cost per unit of service £234.36	Change in total cost of service f18,280.08 f18,280.08 (continued on next page)

Table B1 (continued)	d)				
Stage IIIB Number of patients Service	Service	in service demand per	Total change in number of units	Cost per unit of	Change in total cost of service
6	Ultrasound	pacient. 6		551 VICE £234.36	E8436.96 E8436.96
Stage IIIC Number of patients Service	Service	in service demand per	Total change in number of units	Cost per unit of	Change in total cost of service
-	Ultrasound	pacient. 6	or service 6	service £234.36	E1406.16 E1406.16
Stage IIID Number of patients Service	Service	in service demand per	Total change in number of units	Cost per unit of	total cost of service
-	Whole body + brain CE-CT	patient 8	of service 8	service £428.83	E3430.64 E3430.64
*All 24 Stage IB patien thickness. As a result,	"All 24 Stage IB patients in 2019 were eligible for SLNB Of the 24 pai thickness. As a result, according to the new guidelines, only these	IB Of the 24 patients at UHL in 2019, 2 nes, only these 6 patients out of 24 w	*All 24 Stage IB patients in 2019 were eligible for SLNB Of the 24 patients at UHL in 2019, 2 had lesions with at least one of these features, and 4 had lesions greater than 1.0 mm in Breslow thickness. As a result, according to the new guidelines, only these 6 patients out of 24 would be eligible for SLNB.	features, and 4 had lesion	is greater than 1.0 mm in Breslow
Table B2 Summary	Summary of SLNB guidance changes.				
Stage	UHL Current		2022 Guidelines		
B	Consider SLNB if Breslow thickness > 0.8 mm	Sreslow thickness	Consider SLNB if Breslow thickness 0.8-1.0 mm only lymphovascular invasion, mitotic index of 2 or more	ickness 0.8-1.0 mm only itotic index of 2 or more	Consider SLNB if Breslow thickness 0.8-1.0 mm only if at least one of ulceration, Itymphovascular invasion, mitotic index of 2 or more



Figure A1 UHL melanoma management guidelines.

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