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Scottish Consensus Clinical Management Guidelines for Merkel cell cancer

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Summary Merkel cell carcinoma (MCC) is a rare but highly aggressive neuroendocrine skin cancer with the highest mortality rate among skin cancers. Approximately 40 new cases are reported annually in Scotland, with a rising incidence. A significant proportion of these cases result in loco-regional recurrence and patient mortality.

Historically, few phase 3 randomised controlled trials have been conducted for MCC, and the existing international guidelines are outdated and lack information on the recent advancements in immunotherapy, surgical margins, sentinel lymph node biopsy and post-operative radiotherapy. The 2024 joint guidelines by ESMO-EURA provide comprehensive best practice recommendations; however, there is no UK-specific guideline for the National Health Service (NHS).

To address this gap, the Scottish Consensus Clinical Management Guidelines were developed by a multidisciplinary team of experts, including oncologists, surgeons, radiologists, nurse specialists, pathologists, dermatologists and Mohs surgeons from various NHS Scotland health boards. Initial meetings were held in December 2023, followed by further discussions in 2024,

Abbreviations: AUC, area under the curve; CLND, complete lymph node dissection; CMG, clinical management guideline; FDG-PET-CT, fluorodeoxyglucose positron emission tomography-CT; GTV, gross tumour volume; MCC, Merkel cell carcinoma; MDT, multidisciplinary team; NHS, National Health Service; OTR, organ transplant recipients; PORT, post-operative radiotherapy; SCCMG, Scottish consensus clinical management guidelines; SLNB, sentinel lymph node biopsy; WLE, wide local excision

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including the Scottish Clinical Imaging Network to ratify the use of PET-CT scans for initial imaging.

The final draft of the guidelines was approved at the Scottish skin cancer meeting in March 2025 and is accessible within NHS Scotland through local cancer networks. These guidelines recommend initiating MCC treatment within 8 weeks from diagnosis to improve patient outcomes, representing the first UK-based guideline for MCC. The development process and final guideline, aligned with the RIGHT checklist, aimed at enhancing the multidisciplinary management of MCC in the NHS.

Merkel cell carcinoma (MCC) is an uncommon but highly aggressive cutaneous neuroendocrine tumour with the highest mortality rate among all skin cancers.[1]

Advanced age, immunosuppression, Merkel cell polyomavirus and ultraviolet light exposure are recognised risk factors.[2] Approximately 40 cases a year are reported in Scotland and the incidence is rising[3] with one third of all cases developing loco-regional recurrence and one third dying from MCC.[4]

Only few phase 3 randomised controlled trials have been conducted in MCC. International guidelines produced over the last 2 decades[5] are outdated and do not include the recent advances in immunotherapy or updated reviews on surgical margins, role of sentinel lymph node biopsy (SLNB) and post-operative radiotherapy (PORT).

The 2024 joint guidelines by ESMO-EURA[6] provides a detailed overview of the best practice; however, there is no UK equivalent for optimal clinical guidance. The Scottish consensus clinical management guidelines (SCCMG) brought together multidisciplinary experts from across Scotland to produce a concise and easy to understand pathway outlining the recommended investigations and multidisciplinary management of MCC within secondary or tertiary care settings in the National Health Service (NHS).

Methods

The SCCMG invited expressions of interest from regional health boards across Scotland for individuals involved in the care of patients with MCC. A multidisciplinary team (MDT) was formed, consisting of clinical oncologists, plastic surgeons, oral-maxillofacial surgeons, radiologists, nurse specialists, pathologists, and dermatologists. Owing to the rarity of the disease, no specific patient advocates were available to contribute. At the December 2023 meeting with all the stakeholders, the lead author compiled and presented evidence to create a draft clinical management guideline (CMG). Feedback was sought and two further meetings with updated versions of the guidelines were arranged throughout 2024, including a meeting with the Scottish Clinical Imaging Network for ratification of the use of PET-CT scans in initial imaging.

The final draft of the guidelines was approved at the Scottish skin cancer meeting in March 2025 and is available to access within NHS Scotland via local cancer networks to skin cancer specialists within secondary and tertiary care.

The following sets out a summary of the working process and the final guideline in line with the RIGHT checklist[7] (Appendix 1) The guideline is shown in Figure 1 with accompanying notes in Table 1.

Results

Key health care questions

The scope of the guideline does not include referral for suspected MCC and therefore the starting point is 'histological diagnosis of MCC'—either from an excisional or punch biopsy or lymph node sampling.

Staging of MCC is as per the 8th edition AJCC staging system.[8]

Table 2 outlines the key questions that formed the basis for population, intervention, comparator and outcome (PICO).

Timing

We have adopted a novel approach for including recommended timelines in our CMG. The time to treatment is an important factor in local-regional control and overall survival in MCC. Specifically, several retrospective studies demonstrated that a delay of more than 8 weeks between surgery and the start of radiotherapy increases the risk of recurrence.[9,10] Therefore, a key focus of SCCMG was to improve the efficiency of diagnosis and time to treatment while maintaining the best care.

Staging

Approximately a quarter of patients with MCC present with Stage III or Stage IV disease[4] and clinical examination for in-transit metastasis and regional lymphadenopathy is mandatory.

Radiology staging with CT scan should be performed with contrast if possible. FDG-PET-CT has been shown to upstage an extra 10% of patients compared to CT alone.[11,12] In consultation with the Scottish Clinical Imaging Network, it was decided that PET scans are best interpreted alongside a contrast CT scan and, therefore, to avoid delays in treatment, the SCCMG concluded that clinicians should simultaneously request a CT

with contrast and FDG-PET-CT, although they may be done separately and at different centres.

Wide local excision and surgical margin

Optimal wide local excision (WLE) margins are debated within European and American guidelines,[13,14] as there is conflicting evidence regarding the improvement in outcomes with surgical margins larger than 1 cm.[15,16] This is further confounded by evidence that positive histopathological margins treated with prompt PORT result in equal local-regional control and overall survival compared to negative margins.[4,17,18] The SCCMG concluded that WLE with 1 cm margin is appropriate under the assumption that the patient will receive PORT.

Notably, WLE should take place alongside SLNB if indicated, to expedite the pathway.

Sentinel lymph node biopsy

In clinical and radiological Stage I and II disease (primary lesion only), SLNB provides the most accurate method of detecting microscopic lymph node disease in up to 30% of patients.[19,20] Notably, for immunosuppressed patients, or for tumours in the head and neck and centralised trunk, SLNB can be inaccurate in up to 20% of cases[21,22] and elective neck node dissection or radiotherapy may be considered in cases selected by the MDT but good quality evidence is lacking.

Radiotherapy

MCC is a radiosensitive tumour and radiotherapy is the primary modality of treatment in Australia for stages I-III.[23] In patients who are not fit for surgery and in cases where surgery is too morbid or palliation is required, radiotherapy is a good option. Dose and fractionation and radiotherapy planning are as per the Royal College of Radiologist (Clinical Oncology) guidance.[24]

Lymph node and in-transit disease—management of stage III patients

Stage III encompasses a wide range in MCC from SLNB positive (pN1a) to in-transit metastasis with lymph node disease (pN3). Evidence to support management is lacking and this CMG follows a pragmatic best practice path.

In patients with pN1a disease, complete lymph node dissection (CLND) and PORT appear to have similar outcomes.[25-27] Therefore, radiotherapy to the lymph node basin is recommended rather than performing additional surgery that may delay PORT to the primary site.

For gross lymph node disease (N1b), a CLND is recommended if the patient is sufficiently fit. Radiotherapy can be considered post-operatively in case of high-risk features for local recurrence control; however, there appears to be no overall survival advantage as several of these patients progress to metastatic disease.[28]

For in-transit disease, these patients require specialist MDT discussion.

Post-operative radiotherapy

PORT is recommended in all international guidelines[6] and is associated with significant improvement in local-regional control[29-31] and overall survival[28,29,32] compared to surgery alone based on multiple systemic reviews. Stage I MCC with lower risk lesions may not benefit from PORT due to high rates of local control with surgery alone.

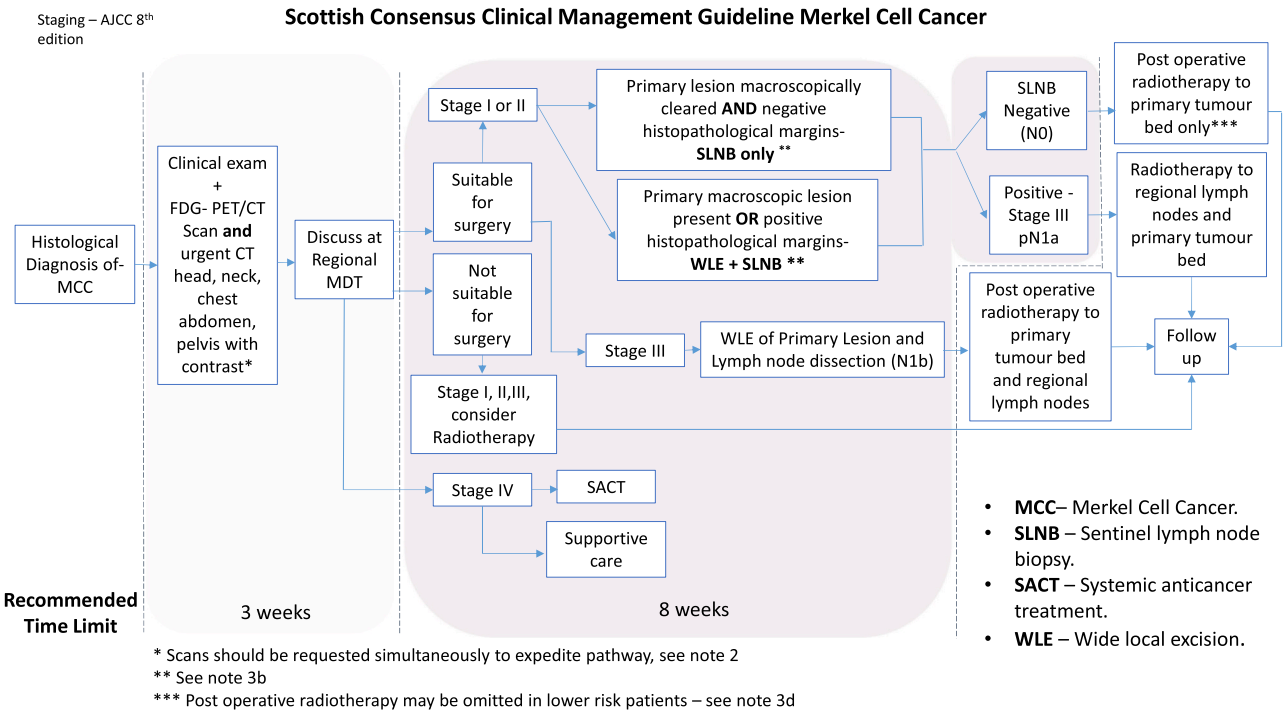

Figure 1 Merkel Cell Cancer Clinical Management Flow Chart.

Table 1 Accompanying Notes for Figure 1.

1. Diagnostic pathway	Primary MCC does not have a distinct clinical appearance, and histopathology may be obtained from punch or excisional biopsies with inadequate surgical margins. Patients should be staged urgently and discussed at MDT prior to further excision.
2. Preferred imaging modality – FDG-PET-CT scan	It is acknowledged by the group that for interpretation purposes, CT scan with contrast alongside a FDG-PET-CT for radiological staging is preferred. Thus, it is recommended to request FDG-PET-CT Scan **and** urgent CT head, neck, chest, abdomen and pelvis with contrast simultaneously.
3. Primary tumour treatment	
3a - Primary Surgery and margins	Surgical excision with a 1 cm clinical margin is recommended. Excision with <1 cm margin followed by PORT is acceptable when wide surgical margins are challenging.
3b - Sentinel Lymph Node Biopsy ± Wide local excision	SLNB is recommended for identifying subclinical nodal disease. In the case of primary macroscopic lesion presence **OR** positive histopathological margins, the group recommended that a WLE may be undertaken in the same procedure. In cases where there are persistent positive margins, patients should proceed to PORT, rather than further re-excision. If SLNB is not available or thought to be unreliable (e.g. in the head and neck region and centralised tumours) or there will be considerable delays, then elective nodal irradiation or completion lymph node dissection may be considered instead.
3c - Radiotherapy for primary tumour	MCC is a radiosensitive tumour and for inoperable cases definitive radiotherapy can be considered as an alternative to surgery. **See notes below regarding radiotherapy.**
3d – Post-operative radiotherapy and radiotherapy timings	PORT should be performed within 8 weeks of surgery. There is some evidence that in patients who underwent PORT, no difference in survival or local recurrence between a positive or negative histological margin were reported. Therefore, in the case of positive or close margins, it is reasonable to proceed to prompt PORT when wide surgical margins are challenging—MDT discussion is recommended. For patients with lower risk of developing lesions, observation instead of PORT can be considered—i.e. small primary tumour (<1 cm); non-head and neck primary site; no lymphovascular invasion and no immunosuppression such as chronic T-cell immunosuppression, HIV, chronic lymphocytic leukaemia and solid organ transplant.
4. Nodal disease and in-transit metastasis	**Nodal disease and in-transit metastasis** (stage III). For pN1a disease (SLNB detected), primary radiotherapy of the regional lymph nodes is the preferred modality. For N1b disease, consider lymph node dissection and PORT. PORT should also be given to primary tumour site if the primary site is known. For N2 or N3 (in-transit metastasis), patient may undergo surgery or radiotherapy, if feasible.
5. Follow-up	
Stages I and II	Three to 6 monthly clinic visits based on risk, with examination for 3 years and thereafter every 12 months for up to 5 years post-treatment. FDG-PET-CT or CT when clinically indicated.
Stage III	Three monthly clinic visits with examination for 3 years and thereafter every 12 months for up to 5 years post-treatment. Imaging every 3 to 6 months based on risk, with CT scan or FDG-PET-CT when clinically indicated.
6. Systemic anticancer treatment	First line preferred treatment is avelumab 800 mg IV, repeat every 14 days until disease progression or unacceptable toxicity. Chemotherapy as a the first or second line can also be administered at the clinician's discretion. Carboplatin AUC4 or AUC5 IV and etoposide 100 mg/m^2 IV Day 1, Day 2 and Day 3. On Days 2 and 3, it can be given orally at a dose of 200 mg/m^2 for up to 6 cycles. Immunotherapy (avelumab) is challenging in organ transplant recipients because of the risk of allograft failure. All cases of MCC in OTR should be discussed with their transplant physicians to ascertain whether minimisation of immunosuppression is feasible. Switching immunosuppression from a calcineurin inhibitor to an mTOR inhibitor may be appropriate.

(*continued on next page*)

Table 1 (*continued*)

7. Radiotherapy	Bolus is used to achieve adequate skin dose. For post-operative treatment, wide margins (3–5 cm) should be used around the surgical bed, when clinically feasible with consideration given to anatomic constraints. Clinical tumour volume for primary tumour is GTV plus 3—5 cm on skin surface and a minimum of 1.5 cm deep to skin. Elective nodal irradiation may be considered in Stage II—**see note 3b.** Definitive treatment—60–66 Gy in 30–33 fractions over 6–6.5 weeks, 50–55 Gy in 20–25 fractions over 4–5 weeks, 45–50 Gy in 20 fractions over 4 weeks and 30–35 Gy in 10 fractions over 2 weeks. Post-operative radiotherapy—50–60 Gy in 25–30 fractions. Various schedules can be offered for palliative radiotherapy (e.g. 8 y/1 fraction, 20 Gy/5 fractions…). Post-operative radiotherapy should commence within 8 weeks.

AUC – area under the curve, **FDG-PET-CT -** fludeoxyglucose positron emission tomography-CT, **GTV** – gross tumour volume, **MCC -** Merkel cell cancer, **MDT** – multidisciplinary team**, OTR** – organ transplant recipients, **PORT -** post-operative radiotherapy**, SLNB -** sentinel lymph node biopsy, **WLE -** wide local excision.

Due to inherent radiosensitivity and to maintain timelines of treatment, the SCCMG agreed that in the case of positive histological margins after a second excision (see Fig. 1) patients should proceed to PORT rather than pursuing negative histological margin with further surgery.

Dose and fractionation and radiotherapy planning are as per the Royal College of Radiologist (Clinical Oncology) guidance.[24]

Follow-up

Patients with MCC at are high risk of recurrence with 90% of the recurrences occurring within 2 years of treatment.[4,33] Therefore, close follow-up is required for the first 2 years. Patients with Stage III disease are at significant risk of metastatic recurrence and routine CT imaging is recommended.[6,14]

Management of stage IV patients

Since the approval of the anti-PD1 immunotherapy—avelumab from a phase II study in 2018, it is currently the first line treatment recommended in metastatic MCC,[34] if the patient is eligible.

Platinum-based chemotherapy has activity against MCC and may also be considered as the first or second line treatment post-immunotherapy.[35]

Discussion

Apart from immunotherapy for Stage IV disease, there have been few advances for MCC over several decades. Guidelines are hindered by the lack of randomised controlled trials and use large retrospective datasets to make recommendations.

The Scottish Consensus Guidelines are no exception and recommendations for this guideline are in significant part pragmatic. Additionally, we can only provide guidance for secondary and tertiary care even though delays through primary referral are problematic. We have not included the use of Mohs surgery owing to its limited availability within NHS Scotland and its place within MCC is uncertain.[36]

Another important consideration is the role of immunosuppression with an increased risk of developing MCC and higher rates of poor outcomes. Moreover, it is commonly a contraindication to immunotherapy.[37] All immunosuppressed patients should be managed jointly with their relevant speciality.

Table 2 PICO questions.

Intervention	Question
Timing	What time scale should investigations and treatment be completed in?
Staging	Optimal clinical and radiological staging method to detect regional and metastatic disease in all patients.
Sentinel lymph node biopsy	Role of sentinel lymph node biopsy in clinical and radiology negative patients (Stages I and II) and management of positive sentinel lymph node biopsy (pN1a) patients.
Surgical margin	Surgical margin in wide local excision for Stage I and II patients.
Radiotherapy	Role of radiotherapy in Stage I-IV patients.
Lymph node and in-transit disease	Management of Stage III patients.
Post-operative radiotherapy	Role of post-operative radiotherapy in Stage I, II and III patients and dose and fractionation.
Follow-up	Follow-up of Stage I-III patients.
Stage IV	Optimal management of Stage IV (metastatic) patient.

For future guidance, the role of adjuvant immunotherapy is unproven but promising in MCC as we await the outcome of the ADMEC-O trial.[38] Furthermore, Australian studies have examined the role of radionuclide therapy in metastatic disease.[39] There are also promising studies that have delved into de-escalation of radiotherapy dose.[40]

For future research, we need a better understanding of the role of Merkel cell polyomavirus as a potential therapeutic target and second line immunotherapy options.

This CMG provides the most up-to-date UK guideline published and introduces a novel emphasis on the timing of investigation to treatment outcome.

Ethical approval

N/A.

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Conflicts of interest

None declared.

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Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.bjps.2025.08.046.

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