Subject: Micrographic (Mohs) Surgery for Cancerous and Noncancerous Lesions		Original Effective Date: 6/26/13
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PREFACE

This Medical Guidance is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the following website: http://www.cms.hhs.gov/center/coverage.asp.

FDA INDICATIONS

Mohs surgery is a procedure and is not regulated by the Food and Drug Administration.

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina medical coverage guidance (MCG) document and provide the directive for all Medicare members. The directives from this MCG document may be followed if there are no available NCD or LCD documents available and outlined below.

A CMS National Coverage Determination (NCD) was not found for mohs surgery. Local coverage determinations (LCD's) are available for Mohs surgery. These LCD's provide coverage for certain diagnoses and indications that include Basal cell, Squamous cell, Basolosquamus cell carcinomas and other skin lesions.

The LCD's further indicate that Mohs micrographic surgery is a technique for the removal of complex or ill-defined skin cancer with histologic examination of 100% of the surgical margins. It requires a single physician to act in two integrated but separate and distinct capacities: surgeon and pathologist. If either of these responsibilities is delegated to another physician who reports the services separately, these codes should not be reported. The Mohs surgeon removes the tumor tissue and maps and divides the tumor specimen into pieces, and each piece is embedded into an individual tissue block for histopathologic examination. Thus a tissue block for Mohs surgery is defined as an individual tissue piece embedded in a mounting medium for sectioning. [2]

Please access the Medicare Local Coverage Determination (LCD) for coverage criteria that may be available in you specific region at: http://www.cms.gov/mcd/search.asp?clickon=search

INITIAL COVERAGE CRITERIA

Mohs micrographic surgery (MMS) may be considered medically necessary and authorized when all of the following criteria are met: [ALL]

- ❑ Mohs' micrographic surgery must be performed by a dermatologic surgeon formally trained in dermatology and fellowship-trained in MMS, cutaneous oncology, and dermatologic surgery. [6 7 8]
- ❑ Diagnosis of Basal Cell, Squamous Cell, or Basalosquamous Cell Carcinomas in any of these anatomic locations where tissue preservation is essential [2 3 6 7]: [ONE]
  - o Mask area of the face (central face, eyelids, eyebrows, periorbital areas, nose, lips, chin, ear, mandible, periauricular areas: temple, skin/sulci);
  - o Forehead, cheeks, and neck;
  - o Genitalia including perineal and perianal;
  - o Hands & feet including nail units;
  - o Scalp

AND

- ❑ Basal cell carcinomas (BCC), squamous cell carcinomas (SCC), or basalosquamous carcinomas that have one or more of the following features [2 3 6 7]: [ONE]
  - o Recurrent tumor; [6]
  - o Aggressive pathology [6]: [ONE]:
    - ◊ For BCC: Morpheaform, micronodular, infiltrative, perineural, metatypical/keratotic
    - ◊ For SCC: Sclerosing, small cell, poorly differentiated, perineural, infiltrating, pagetoid
  - o Size > 2.0 cm in diameter; [6]
  - o Positive margins on recent excision; [6]
  - o Poorly defined clinical borders; [6]
  - o Irradiated skin; [6]
  - o Immunosuppresed; [6]
  - o In a chronic scar (Marjolin's ulcer); [6]

- Associated with genetic syndromes [6]: [ONE]
    - ◊ xeroderma pigmentosum;
    - ◊ basal cell nevus syndrome

OR

- ❑ Other Skin Lesions [2 3 6 7 29 30]:
    - Adenocystic carcinoma of the skin; [6]
    - Adnexal carcinoma [3]
    - Apocrine/eccrine carcinoma of the skin [3]
    - Atypical fibroxanthoma; [6]
    - Bowen's disease (squamous cell carcinoma in situ) [3]
    - Dermatofibrosarcoma protuberans; [6 29]
    - Extramammary Paget's disease; [6]
    - Keratoacanthoma; [6]
    - Leiomyosarcoma or other spindle cell neoplasms of the skin; [6]
    - Malignant fibrous histiocytoma; [3]
    - Merkel cell carcinoma; [6 30]
    - Microcystic adnexal carcinoma; [6]
    - Mucinous carcinoma [3]
    - Sebaceous gland carcinoma; [3]
    - Verrucous carcinoma [6]

- ❑ Melanoma in situ or lentigo maligna [2 3 6 7]: [ONE]
    - conventional excision with appropriate margins is not possible due to anatomical or technical reasons

CONTINUATION OF THERAPY

N/A

COVERAGE EXCLUSIONS

Mohs micrographic surgery is not covered if the above criteria are not met.

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

Mohs micrographic surgery (MMS) is a microscopically guided procedure during which a specially trained surgeon removes skin cancers that are difficult to treat by conventional means due to their location, histopathology, size, local invasiveness, or tendency to recur after primary therapy. Thin, horizontal layers of cancerous skin tissue are excised in a staged procedure, and each layer is microscopically examined by the

surgeon. The procedure is repeated until no cancer cells remain. The goal of the surgery is to achieve a cure while preserving as much normal skin tissue as possible.

MMS is performed in an outpatient surgical unit or physician's office by a qualified Mohs surgeon. A surgical laboratory equipped for processing of the surgical specimen, including the sectioning, orientation, mapping, coding, preparation of frozen section using a cryostat, and staining, must be adjacent to or in proximity to the operating suite. A histology technician may process the specimen, and the Mohs surgeon serves as the pathologist for slide interpretation. There are two types of techniques described for MMS:

- *Fresh Tissue Technique*

After induction of local anesthesia, the visible tumor is removed. Thin layers of tissue are excised in an elliptical-shaped manner surrounding the tumor, and histological examination is performed. If residual cancer is seen, additional surgery is carried out for further removal. The procedure is continued until all cancer is removed, preserving normal surrounding tissue. In most instances, repair or reconstruction of the wound is necessary for healing.

- *Fixed Tissue Technique*

Fixed tissue technique is used in less than 5% of cases. The major difference between this technique and fresh tissue technique is the application of 40% zinc chloride paste after tumor debulking with a curette. This eliminates the need for local anesthetic and creates a blood-free surgical field. The area is then covered with an occlusive dressing, and the paste is allowed to penetrate the wound for 6–24 hours. After fixation, the same procedure is followed as for fresh tissue technique. After the tissue is examined histologically, additional fixative is applied for another 6–24 hours to the areas with residual tumor. The residual tumor is removed in successive layers until a tumor-free plane is achieved. The final layer of fixed tissue is allowed to separate naturally, with healing by way of granulation and epithelialization or delayed reconstruction. [1]

GENERAL INFORMATION

Summary of Medical Evidence

Basal Cell Carcinoma (BCC) & Squamous Cell Carcinoma (SCC)

Pugliano and associates (2010) conducted a retrospective review to report the outcome of patients with high-risk SCCs treated with MMS. Two hundred fifteen patients with 260 high-risk cutaneous SCCs were reviewed in a single-center retrospective study, considering rates of recurrence, metastasis, and death. Cases were analyzed according to sex, age, immunocompetency status, tumor depth, lesion site, perineural disease, death rate, cause of death, secondary SCC, and melanoma. Seventy-seven percent of patients were male; 23% were female. Average age was 70.6. Twenty percent of patients were immunosuppressed. Mean follow-up was 3.9 years. There were three local recurrences (1.2%). Twelve (4.6%) tumors involved named nerve trunks. In eight of these cases, adjuvant radiation therapy was employed. Six (2.3%) tumors metastasized, with one fatality from disease. Seventy-five percent of patients developed another cutaneous SCC, and 7.7% developed a subsequent malignant melanoma. The authors concluded that MMS is an effective treatment for high-risk cutaneous SCC.

This represents the largest single-center study of high-risk SCC supporting the use of MMS. Adjuvant radiotherapy was reserved for large-nerve perineural disease. There was a low recurrence rate and disease-specific mortality. Prompt recognition of metastatic disease allowed for curative therapy. Patients with one high-risk SCC are likely to develop secondary primary SCC and melanoma. [31]

Mosterd and colleagues (2008) performed a prospective randomised controlled trial to compare the effectiveness of surgical excision with Mohs' micrographic surgery (MMS) for the treatment of primary and recurrent facial BCC. Between Oct 5, 1999, and Feb 27, 2002, 408 primary BCCs (pBCCs) and 204 recurrent BCCs (rBCCs) in patients from seven hospitals in the Netherlands were randomly assigned to surgical excision or MMS. Randomization and allocation was done separately for both groups by a computer-generated allocation scheme. Tumours had a follow-up of 5 years. Analyses were done on an intention-to-treat basis. The primary outcome was recurrence of carcinoma, diagnosed clinically by visual inspection with histological confirmation. Secondary outcomes were determinants of failure and cost-effectiveness. Of the 397 pBCCs that were treated, 127 pBCCs in 113 patients were lost to follow-up. Of the 11 recurrences that occurred in patients with pBCC, seven (4.1%) occurred in patients treated with surgical excision and four (2.5%) occurred in patients treated with MMS (log-rank test chi(2) 0.718, p=0.397). Of the 202 rBCCs that were treated, 56 BCCs in 52 patients were lost to follow-up. Two BCCs (2.4%) in two patients treated with MMS recurred, versus ten BCCs (12.1%) in ten patients treated with surgical excision (log-rank test chi(2) 5.958, p=0.015). The difference in the number of recurrences between treatments was not significant for pBCC, but significantly favored MMS in rBCC. In pBCC, Cox-regression analysis showed no significant effects from risk factors measured in the study. In rBCC, aggressive histological subtype was a significant risk factor for recurrence in the Cox-regression analysis. For pBCC, total treatment costs were euro1248 for MMS and euro990 for surgical excision, whereas for rBCC, treatment costs were euro1284 and euro1043, respectively. Dividing the difference in costs between MMS and surgical excision by their difference in effectiveness leads to an incremental cost-effectiveness ratio of euro23 454 for pBCC and euro3171 for rBCC. The investigators concluded that MMS is preferred over surgical excision for the treatment of facial rBCC, on the basis of significantly fewer recurrences after MMS than after surgical excision. [14]

Smeets and colleagues (2004) performed a randomised controlled trial to investigate the types of facial basal-cell carcinomas in which MMS was more effective than surgical excision (SE). 408 primary and 204 recurrent facial carcinomas (374 and 191 patients, respectively) were analyzed separately in this prospective randomised study. Patients were assigned SE or MMS (each 204 primary, 102 recurrent), and received treatment at two hospitals in the Netherlands. The primary outcome was recurrence of carcinoma. Analysis was by intention to treat. Of the basal-cell carcinomas included in the trial, 397 primary (198 MMS, 199 SE) and 201 recurrent (99, 102) tumours were actually treated. Of patients with primary carcinomas, 21 had both MMS and SE on different tumours. Nine with recurrent carcinomas had both treatments on different skin tumours. 66 primary and 13 recurrent carcinomas were lost to follow-up. Of the primary carcinomas, five (3%) recurred after SE compared with three (2%) after MMS during 30 months of follow-up. Of the recurrent carcinomas, three (3%) recurred after SE and none after MMS during 18 months of follow-up. Four recurrent carcinomas randomly assigned to the SE group were treated with MMS. Although both differences favored MMS, they were not significant

(primary, difference 1% [95% CI -2.5% to 3.7%], p=0.724; recurrent, 3.2% [-2.0% to 5.0%], p=0.119). The authors concluded that no definitive conclusion on recurrence rates of primary or recurrent basal-cell carcinomas is possible, but recurrence rates were lower after MMS than after SE. [15]

Muller and colleagues (2009) published the results of a randomised trial that compared MMS to standard surgery in patients with basal cell carcinoma. The purpose was to determine whether MMS leaves smaller surgical defects than standard surgery. Patients were randomly assigned to MMS or standard surgery. In the standard surgery group the BCCs were excised with 4-mm margins. In the MMS group, tumors were excised with 2-mm margins and subsequent stages of MMS until the tumor was completely removed. An observer unaware of the treatment allocation calculated the defect size. The main outcome measure was defect size in mm(2). The median area of the surgical defects in the MMS group was 116.6 mm(2), versus 187.7 mm(2) in the standard surgery group (95% confidence interval for difference=61-126, p<.001). The authors concluded that MMS is a tissue sparing treatment. [13]

Chren and colleagues (2007) sought to compare quality-of-life outcomes of treatments for cutaneous basal cell carcinoma and squamous cell carcinoma (typically called nonmelanoma skin cancer (NMSC). A prospective cohort study of 633 consecutive patients with NMSC diagnosed in 1999 and 2000 and followed for 2 years after treatment at a university-based private practice or a Veterans Affairs clinic was performed. The main outcome was tumor-related quality of life 1 to 2 years after therapy, measured with the 16-item version of Skindex, a validated measure. Skindex scores vary from 0 (best) to 100 (worst) in three domains: Symptoms, Emotions, and Function. Treatments were electrodessication and curettage (ED&C) in 21%, surgical excision in 40%, and Mohs surgery in 39%. Five hundred and eight patients (80%) responded after treatment. Patients treated with excision or Mohs surgery improved in all quality-of-life domains, but quality of life did not improve after ED&C. There was no difference in the amount of improvement after excision or Mohs surgery. For example, mean Skindex Symptom scores improved 9.7 (95% CI: 6.9, 12.5) after excision, 10.2 (7.4, 12.9) after Mohs surgery, and 3.4 (-0.9, 7.6) after ED&C. The authors concluded that, for NMSC, quality-of-life outcomes were similar after excision and Mohs surgery, and both therapies had better outcomes than ED&C. [16]

Chren and colleagues (2011) sought to determine long-term tumor recurrence rates after treatment of primary nonmelanoma skin cancer (NMSC). A prospective study of an inception cohort observed for a median of 6.6 years after treatment was conducted on 495 patients with 616 primary NMSCs diagnosed in 1999 and 2000 and treated with electrodessication and curettage (ED&C), excision, or Mohs surgery. Follow-up was available for 608 tumors (99%). The main outcome measure was tumor recurrence, determined by medical record review, with validation by clinical examination. The results showed that the mean age at diagnosis was 71 years; 97% were men. Overall, 127 tumors were treated with ED&C (20.9%); 309 with excision (50.8%); and 172 with Mohs surgery (28.3%). Over the course of the study, 21 tumors recurred (3.5% [95% confidence interval (CI), 2.2%-5.2%]): 2 after ED&C (1.6% [95% CI, 0.2%-5.6%]), 13 after excision (4.2% [95% CI, 2.2%-7.1%]), and 6 after Mohs surgery (3.5% [95% CI, 1.3%-7.4%]). The authors concluded that recurrence of primary NMSC

after treatment occurred in less than 5% of tumors. The recurrence rate after ED&C was lower than expected, and the recurrence rate after Mohs surgery was higher than expected. These findings may be related to the risk for recurrence in the treatment groups. [17]

Leibovitch and colleagues (2005) published the results of a large series of patients with cutaneous lip tumours treated with MMS in Australia between 1993 and 2002. This prospective multicentre case series included all patients with cutaneous lip tumours who were monitored by the SCFA. The main outcome measures were patient demographics, reason for referral, duration of tumour, site, preoperative tumour size and postoperative defect size, recurrences prior to MMS, histological subtypes, perineural invasion and 5-year recurrence after MMS. There were 581 patients (66.1% women and 33.9% men, P < 0.0001) with a mean +/- SD age of 58 +/- 15 years. The upper lip was the most common site involved (81.1%). Basal cell carcinoma (BCC) was diagnosed in 82.3%, squamous cell carcinoma (SCC) in 16.5%, Bowen's disease (BD) in 0.7% and microcystic adnexal carcinoma (MAC) in 0.5% of cases. BCC was more common on the upper lip and in women, whereas SCC was more common on the lower lip and in men (P < 0.0001). Most upper lip tumours occurred in women (75.4%), whereas most lower lip tumours occurred in men (73.6%). SCC was associated with a larger tumour and postoperative defect size compared with the other tumours. The 5-year recurrence for BCC was 3.0%, and there were no cases of recurrence for SCC, BD or MAC. The authors concluded that BCC was the most common cutaneous lip tumour managed by MMS, and was significantly more common on the upper lip and in women. The low 5-year recurrence rate emphasizes the importance of margin-controlled excision. [18]

Leibovitch and colleagues (2005) sought to evaluate the incidence, features, and outcomes of BCC with perineural invasion (PNI) in patients treated with Mohs micrographic surgery (MMS). A prospective, multicenter case series included all patients in Australia treated with MMS for BCC with PNI and who were monitored by the Skin and Cancer Foundation Australia between 1993 and 2002. The parameters recorded were patient demographics, reason for referral, duration of tumor, site, preoperative tumor size, recurrence before MMS, histologic subtypes, postoperative defect size, and recurrence at 5 years after MMS. Two-hundred eighty-three patients were diagnosed with PNI. Most cases occurred in male patients (61%; P = .006) and in previously recurrent tumors (60.4%; P < .001). The infiltrating, morpheic, and basosquamous subtypes were more likely to be associated with PNI (P < .0001). Tumor sizes before excision and postoperative defect sizes were significantly larger in cases with PNI compared with cases with no PNI (P < .001 for both parameters), as was the mean number of Mohs excision levels. Seventy-eight patients completed a 5-year follow-up period after MMS, and 6 of them (7.7%) were diagnosed with recurrence. PNI is an uncommon feature of BCC. When present, PNI is associated with larger, more aggressive tumors, and the risk of 5-year recurrence is higher. This emphasizes the importance of tumor excision with margin control and long-term patient monitoring. [19]

Another large prospective multicenter case series by Leibovitch and colleagues (2005) was published to report the clinical findings of all patients with BCC treated with Mohs micrographic surgery (MMS). The study included 11,127 patients (47% females and 53% males) with a mean age of 62 years (range, 15-98 years). In

43.8% of cases BCC was a recurrent tumor. Most of the tumors (98.3%) were on the head and neck area, most commonly on the nose (39%), cheek and maxilla (16.5%), periocular area (12.7%), and auricular region (11.4%). The most common histologic subtypes were infiltrating (30.7%), nodulocystic (24.2%), and superficial (13.6%). Previously recurrent tumors were larger than primary tumors ($P < .001$), had a larger postexcision defect and more subclinical extension, and required more levels of excision ($P < .001$). This large prospective series of BCC managed by MMS is characterized by a high percentage of high-risk tumors. Most tumors were located in the mid-facial area and the histologic subtype was mainly infiltrating or nodulocystic. That previously recurrent tumors were larger and demonstrated a more extensive subclinical extension compared with primary tumors emphasizes the importance of initial tumor eradication with margin control. [20]

Melanoma

Then and colleagues (2009) performed a retrospective, multicenter, noncomparative case series To report early cure rates for periocular melanoma using Slow-Mohs surgery with en-face margin sectioning. Fourteen patients underwent 14 Slow-Mohs procedures for eight lentigo maligna, one nodular, and one superficial spreading melanoma, and four lentigo maligna, 12 primary, and two recurrent tumors. The most common site was the lower eyelid (8/14, 57.1%). Breslow thickness ranged from 0.27 to 1.70 mm, with four cases less than 0.76 mm and one case greater than 1.5 mm. Five cases were a Clark level II or greater. Complete excision was achieved with one level (6 cases) or two or three levels (8 cases), with 2- to 3-mm margins at each level in all but one case. With median follow-up of 36 months, there were two local recurrences (2/14, 14.3%). The authors concluded that Slow-Mohs with en-face sections achieves similar early cure rates to previously published margin-controlled excision techniques. Narrow margins of excision can optimize tissue preservation without compromising outcome. [21]

Bene and colleagues (2008) published the results of a prospective study evaluating if margins determined to be clear by Mohs' surgery were clear by subsequent paraffin-embedded sections (gold standard for determining margins) and to compare cure rate with available data for Mohs' standard excision. A total of 167 patients with MIS participated in the study and were treated by Mohs' with subsequent evaluation over a period of 12 years. Overall, the authors reported of 167 cases of MIS, eight cases had a positive margin on paraffin-embedded sections after margins on Mohs' frozen sections were called "clear", resulting in a 95.1% clearance rate. After one re-excision all eight tumors had clear margins on paraffin-embedded sections. Cure rates reported for mean follow-up of 50 months and of 63 months were 98.6% and 98.2% respectively. [9]

McKenna and colleagues (2006) conducted a review evaluating the clinical features, histopathology and various treatments for lentigo maligna, a subtype of melanoma in situ that develops on sun-damaged skin. In the authors opinion standard excision using 5 mm margins is insufficient in many cases, and recurrence rates with standard excision ranges from 8 to 20%. Mohs' surgery and staged excision may offer improved margin control and lower recurrence rates. [11]

Bricca and colleagues (2005) conducted a prospective case series consisting of 625 patients with primary cutaneous melanoma or melanoma in situ of the head and neck treated with MMS technique. Follow-up was conducted biannually for the majority of cases with invasive melanoma, and annually for patients with melanoma in situ. The mean follow-up for the group was 58 months. The results of their study suggest that MMS achieved five-year local recurrence rates, metastasis rates, and disease- specific survival rates comparable to or better than historical controls after Breslow thickness stratification. The size of the surgical margin required for complete excision was significantly related to tumor thickness but not tumor size or specific location. [10]

Other:

A systematic review was conducted (2012) to summarize evidence about the recurrence of dermatofibrosarcoma protuberans (DFSP) following Mohs micrographic surgery (MMS). The review searched MEDLINE, Cochrane Library, EMBASE, Pascal, Biosis, CisMef, BDSP, Scopus, and Web of Knowledge databases for the period January 1, 1995, to August 31, 2011. Randomized controlled trials or nonrandomized trials comparing the recurrence of DFSP among patients undergoing MMS vs wide local excision were selected. Twenty-three nonrandomized trials (4 comparative and 19 noncomparative) were included. Moderate-quality evidence (level B) was found for recurrence of DFSP after MMS (1.11%; 95% CI, 0.02%-6.03%) vs after wide local excision (6.32%, 95% CI, 3.19%-11.02%). A mean raw recurrence rate of 1.03% (95% CI, 0.37%-2.22%) was found after MMS among 19 nonrandomized noncomparative trials (low-quality evidence [level C]). The mean follow-up periods ranged from 26 to 127 months. The mean time to recurrence was 68 months. The review concluded that a weak recommendation is given in favor of MMS or similar surgical techniques with meticulous histologic evaluation of all margins as the first-line therapy for DFSP, particularly in recurrence-prone regions. [27]

Thomas and colleagues (2007) conducted a retrospective review to evaluate the effectiveness of MMS in the treatment of six rare aggressive cutaneous malignancies as seen by Mohs surgeons working at a referral center. Retrospective chart review of 26,000 cases treated with MMS at the Geisinger Medical Center Department of Dermatology during a 16-year period with the following diagnoses: poorly differentiated squamous cell carcinoma (PDSCC), dermatofibrosarcoma protuberans (DFSP), microcystic adnexal carcinoma (MAC), extramammary Paget's disease (EMPD), Merkel cell carcinoma (MCC), and sebaceous carcinoma (SEB CA). Patient demographic data, tumor measurements, treatment characteristics, and marginal recurrence rates were compiled and evaluated. The mean numbers of cases identified per year for each tumor type were as follows: PDSCC, 6.19; DFSP, 2.44; MAC, 1.63; and EMPD, 0.63. For PDSCC, 85 cases were available for follow-up with a local recurrence rate of 6% at a mean follow-up time of 45 months. For DFSP, there were 35 cases with no local recurrence at a mean follow-up of 39 months. For MAC, there were 25 cases with a local recurrence rate of 12% at a mean follow-up of 39 months. For EMPD, there were 10 cases with no local recurrences at a mean follow-up of 34 months. The authors concluded that the data on PDSCC, DFSP, MAC, and EMPD,

combined with other studies in the literature, show that MMS is the most effective therapy for these rare aggressive cutaneous malignancies. [32]

A meta-analysis was conducted (2006) to determine the effect of adjuvant local irradiation on (1) disease recurrence and (2) survival rates in Merkel cell carcinoma (MCC). The following criteria for inclusion were applied to each potential patient: (1) a histopathologic diagnosis of MCC; (2) a single, primary tumor arising on the skin, for which (3) the primary treatment was surgical excision (local excision, wide excision, or Mohs surgery) with or without the use of adjuvant irradiation (to the tumor bed); (4) following surgery, negative (clear) surgical margins were obtained; (5) during the postoperative follow-up period, disease recurrence, progression, and survival and/or duration of event-free interval was documented with (6) a minimum follow-up of 1 month. A total of 1254 patients were included in the analysis. Statistically significant reductions in local (hazard ratio [HR], 0.27; P < .001) and regional (HR, 0.34; P < .001) recurrence were observed among patients treated with combination therapy compared with surgery alone. Similar rates of distant metastasis were observed between treatment groups (HR, 0.79; P = .31). Overall survival rates were 87% (1 year) and 49% (5 years). Cause-specific survival rates were 90% (1 year) and 62% (5 year). In general, differences in overall (HR, 0.78; P = .16) and cause-specific (due to MCC: HR, 0.72; P = .14) survival rates between treatment groups did not reach statistical significance. A subgroup analysis that excluded single-patient case reports and studies of only 1 treatment group revealed a significant overall (HR, 0.63; P = .02) and cause-specific (HR, 0.62; P = .04) survival advantage after treatment with combination therapy. The review concluded that surgery plus local adjuvant irradiation was associated with significantly lower rates of local and regional recurrence of MCC than surgery alone. Prospective investigation is needed to clarify the presence of a survival benefit from combination therapy. [28]

Hayes, Cochrane, UpToDate, MD Consult etc.

Cochrane

In 2007 a Cochrane review was published to assess the effects of treatments for basal cell carcinoma. Inclusion criteria were adults with one or more histologically proven, primary basal cell carcinoma. The primary outcome measure was recurrence at three to five years, measured clinically. The secondary outcome included early treatment failure within six months, measured histologically. Adverse treatment effects included aesthetic appearance and pain during and after treatment. Twenty seven studies were identified. Only one RCT of surgery versus radiotherapy had primary outcome data at four years, showing significantly more persistent tumours and recurrences in the radiotherapy group as compared to the surgery group, (RR 0.09, 95%CI, 0.01 to 0.69). One study found no significant difference for recurrence at 30 months when Moh's micrographic surgery was compared to surgery for high risk facial BCCs, (RR 0.64, 95%CI 0.16,2.64). One study of methylaminolevulinate photodynamic therapy (MAL PDT) versus cryotherapy found no significant difference in recurrences in the MAL PDT group when compared to cryotherapy at one year (RR 0.50, 95% CI 0.22,1.12). Cryotherapy showed no significant difference in recurrences at one year when compared to surgery on one small study. When radiotherapy was compared to cryotherapy there were significantly fewer recurrences at one

year in the radiotherapy group compared to the cryotherapy group. Short-term studies suggest a success rate of 87 to 88% for imiquimod in the treatment of superficial BCC using a once-daily regimen for 6 weeks and a 76% treatment response when treating nodular BCC for 12 weeks, when measured histologically. The authors concluded that overall there has been very little good quality research on treatments for BCC. Most trials have only evaluated BCCs in low risk locations. Surgery and radiotherapy appear to be the most effective treatments with surgery showing the lowest failure rates. Although cosmetic outcomes appear good with PDT, long term follow up data are needed. Other treatments might have some use but few have been compared to surgery. An ongoing study comparing imiquimod to surgery should clarify whether imiquimod is a useful option. [22]

Another Cochrane review was conducted (2012) to compare the effectiveness, cost, complications and acceptability of periocular basal cell carcinoma (BCCs) when operated by moh's micrographic surgery (MMS) or surgical excision (SE). The search included CENTRAL (which contains the Cochrane Eyes and Vision Group Trials Register) (The Cochrane Library 2011, Issue 11), MEDLINE (January 1950 to November 2011), EMBASE (January 1980 to November 2011), the metaRegister of Controlled Trials (mRCT) (www.controlled-trials.com), ClinicalTrials.gov (www.clinicaltrials.gov) and the WHO International Clinical Trials Registry Platform (ICTRP) (www.who.int/ictrp/search/en). There were no date or language restrictions in the electronic searches for trials. The electronic databases were last searched on 23 November 2011. Randomised controlled trials (RCTs) comparing SE with MMS for treatment of periocular BCC were searched. No studies that met the inclusion criteria for this review were found and therefore none were included for analysis. Results of non-randomised studies describing the individual techniques are reported. No reliable conclusions could be reached regarding which method of treatment (SE or MMS) resulted in a lower recurrence or complication rate for periocular BCC. No studies were found comparing the cost of either method directly. High quality RCTs are therefore needed to improve the evidence base for the management of this condition. [26]

Hayes Medical Technology Directory

A Hayes Medical Technology Directory report indicates that Mohs micrographic surgery (MSS) results in higher rates of cure and lower recurrence rates compared with conventional therapies such as simple excision, electrodesiccation and curettage, and radiotherapy. MMS is a medically appropriate treatment for carefully selected, histopathologically confirmed primary or recurrent basal cell carcinoma's and squamous cell carcinoma's of the skin that meet any of the following criteria: at high risk for recurrence due to anatomical location, indistinct clinical margins, histopathology, biological aggressiveness, invasiveness, and/or size; located in areas where tissue preservation is important; have perineural involvement. This Hayes report was archived in 2006. [1]

UpToDate:

UpTo Date has reports on the topic of Mohs Surgery that outline the following recommendations [6 7 8]:

- Mohs surgery is most commonly performed to treat basal cell and squamous cell carcinomas at high risk of recurrence. Mohs surgery is also indicated for other skin malignancies such as dermatofibrosarcoma protuberans, microcystic adnexal carcinoma, and extramammary Paget disease, and for lentigo maligna.
- Mohs micrographic surgery is the treatment of choice for high-risk localized cutaneous SCCs and SCCs located in cosmetically sensitive or critical areas because of its high cure rate and ability to spare normal tissue. Reported five-year cure rates for primary and recurrent SCCs are about 97 and 90 to 94 percent respectively. For all categories of high-risk SCCs, cure rates are consistently higher with Mohs surgery than with other modalities
- Mohs surgery is indicated for primary BCCs with features that increase risk for recurrence. The tissue-sparing effect of Mohs surgery is also useful in cosmetically sensitive or functionally critical areas. Recurrent BCCs, especially those located in high-risk sites, are candidates for Mohs surgery, particularly because recurrent tumors tend to develop more aggressive histologic subtypes.
- Mohs surgery is not indicated for small primary BCCs located on the trunk or extremities that lack aggressive clinical or pathological features because other procedures have similar efficacy and are less time-consuming and less costly
- Mohs surgery offers several advantages over standard surgical excision, including lower recurrence rates for high risk tumors, maximal tissue preservation in cosmetically and anatomically sensitive areas, and immediate reconstruction in most cases. This surgery requires a highly qualified clinician with expertise in the management of high risk skin cancers, a fully certified Mohs laboratory, and specifically trained histotechnician and nursing staff.
- The use of Mohs surgery for treatment of melanoma remains controversial. There are no clinical trials comparing standard excision to MMS. In a consecutive series of 625 patients with head and neck melanoma treated with MMS and followed up for a mean of 58 months, recurrence, metastasis, and disease-specific survival rates were similar or better than historical controls treated with wide excision.
- MMS may be a treatment option for lentigo maligna, a type of melanoma in situ, because of its poorly defined clinical borders, unpredictable subclinical extension, head and neck location requiring tissue conservation, and propensity for recurrence.

Professional Organizations

American Academy of Dermatology (AAD), American College of Mohs Surgery (ACMS), American Society for Dermatologic Surgery Association ASDSA), and the American Society for Mohs Surgery (ASMS) [3]

The AAD, ACMS, ASDSA and ASMS published appropriate use criteria for Mohs micrographic surgery in 2012.The report addresses the appropriate use of Mohs micrographic surgery (MMS) in the treatment of cutaneous neoplasms and synthesizes evidence-based medicine, clinical practice experience, and expert judgment. 270 scenarios for which Mohs micrographic surgery (MMS) is frequently considered based on tumor and patient characteristics were reviewed. The criteria reflects the rating of appropriateness of MMS for each of these clinical scenarios by a ratings panel in a process based on the appropriateness method developed by the RAND Corp (Santa Monica, CA)/University of California-Los Angeles (RAND/UCLA). At the conclusion of the rating process, consensus was reached for all 270 (100%) scenarios by the Ratings Panel, with 200 (74.07%) deemed as appropriate, 24 (8.89%) as uncertain, and 46 (17.04%) as inappropriate. The ratings category

summary indicated that MMS is appropriate based on specific criteria for basal cell carcinoma, squamous cell carcinoma, lentigo maligna, melanoma in situ and less common skin cancers.

The American Academy of Dermatology (AAD) [1 4]

The AAD published Guidelines of Care for Mohs Micrographic Surgery in 1995. These guidelines indicate that there are multiple, well-accepted surgical and nonsurgical approaches for the treatment of skin cancer, and that certain types of tumors may require a more precise level of treatment. MMS was deemed appropriate for BCCs of the skin with the following characteristics:

- High risk for local recurrence:
  - Ill-defined clinical borders
  - Anatomical location in sites with a high risk for recurrence when treated by other methods, including periorbital and canthal regions, central third of face, columella, periauricular-tragal, postauricular sulcus, perioral region, and the nasofacial sulcus and perinasal area
  - History of incomplete removal
  - Previous radiotherapy
  - Previous recurrence
  - Large size
  - Histologic pattern: Morpheaform, keratinizing, metatypical, infiltrating, contiguous tumors (BCC and SCC), multicentric tumors, deep tissue or bone involvement; perineural or perivascular involvement
- Tumor located in areas where tissue preservation is important: Nasal tip and alae, cutaneous and vermilion portions of the lips, eyelids, auricular helix and canal, hands and feet, genitalia).
- Rapid growth or aggressive behavior, tumors in immunosuppressed patients, and field fire

MMS may be appropriate for SCCs of the skin with the following characteristics:

- High risk for local recurrence:
  - Ill-defined clinical borders
  - Anatomical location in sites with a high risk for recurrence: Periorbital and canthal regions, central third of face, columella, periauricular-tragal, postauricular sulcus, lower extremities, genitalia, temple, scalp, lip, mucosa, nail bed and matrix
  - History of incomplete removal
  - Certain radiation-induced tumors
  - Large size
  - Perineural or perivascular invasion
  - Anaplastic histological differentiation
  - Deep tissue or bone involvement
- Tumor located in areas where tissue preservation is important: Nasal tip and alae, cutaneous and vermilion portions of the lips, eyelids, auricular helix and canal, hands and feet, genitalia, and nail unit/periungual area.
- Tumors associated with a high risk of metastasis: Tumors arising in SCC in situ (Bowen's disease), discoid lupus erythematosus, chronic osteomyelitis, lichen sclerosis et atrophicus, thermal or radiation injury, chronic sinuses and ulcers, and the adenoid type.
- Other:
  - Tumors displaying rapid growth or aggressive behavior

- Tumors in immunosuppressed patients
- Tumors of long-standing duration
- Tumors associated with certain genodermatoses

The American College of Mohs' Micrographic Surgery (ACMS) [5]

ACMS has established requirements for the training of physicians in MMS. While any board certified dermatologist may perform Mohs surgery, only members of the American College of Mohs Surgery (ACMS) have undergone rigorous fellowship training. Chosen through an extremely competitive review and selection process, fellows are required to complete an intensive 1 or 2-year post-residency ACMS fellowship training program.

The National Cancer Institute (NCI) [23] [24]

The NCI PDQ outlines treatment for skin cancer that includes mohs surgery:

- Squamous Cell Carcinoma: Mohs micrographic surgery is best suited to the management of tumors in cosmetically sensitive areas or for tumors that have recurred after initial excision (e.g., eyelid periorbital area, nasolabial fold, nose-cheek angle, posterior cheek sulcus, pinna, ear canal, forehead, scalp, fingers, and genitalia).
- Basal Cell Carcinoma: It is best suited to management of tumors in cosmetically sensitive areas or for tumors that have recurred after initial excision (e.g., eyelid periorbital area, nasolabial fold, nose-cheek angle, posterior cheek sulcus, pinna, ear canal, forehead, scalp, fingers, and genitalia). It is also often used to treat tumors with poorly defined clinical borders.

National Comprehensive Cancer Network (NCCN) [25]

The 2012 NCCN Guidelines for basal cell and squamous cell skin cancer outline that mohs surgery is the recommended treatment option for high risk tumors.

CODING INFORMATION

CPT	**Description:** Mohs micrographic surgery is a technique for the removal of complex or ill-defined skin cancer with histologic examination of 100% of the surgical margins. It requires a single physician to act in two integrated but separate and distinct capacities: surgeon and pathologist. If either of these responsibilities is delegated to another physician who reports the services separately, these codes should not be reported. The Mohs surgeon removes the tumor tissue and maps and divides the tumor specimen into pieces, and each piece is embedded into an individual tissue block for histopathologic examination. Thus a tissue block for Mohs surgery is defined as an individual tissue piece embedded in a mounting medium for sectioning.

17311	Mohs micrographic technique, including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and histopathologic preparation including routine stain(s) (eg, hematoxylin and eosin, toluidine blue), head, neck, hands, feet, genitalia, or any location with surgery directly involving muscle, cartilage, bone, tendon, major nerves, or vessels; first stage, up to 5 tissue blocks
17312	Mohs micrographic technique, including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and histopathologic preparation including routine stain(s) (eg, hematoxylin and eosin, toluidine blue), head, neck, hands, feet, genitalia, or any location with surgery directly involving muscle, cartilage, bone, tendon, major nerves, or vessels; each additional stage after the first stage, up to 5 tissue blocks (list separately in addition to code for primary procedure)
17313	Mohs micrographic technique, including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and histopathologic preparation including routine stain(s) (eg, hematoxylin and eosin, toluidine blue), of the trunk, arms, or legs; first stage, up to 5 tissue blocks
17314	Mohs micrographic technique, including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and histopathologic preparation including routine stain(s) (eg, hematoxylin and eosin, toluidine blue), of the trunk, arms, or legs; each additional stage after the first stage, up to 5 tissue blocks (list separately in addition to code for primary procedure)
17315	Mohs micrographic technique, including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and histopathologic preparation including routine stain(s) (eg, hematoxylin and eosin, toluidine blue), each additional block after the first 5 tissue blocks, any stage (list separately in addition to code for primary procedure
17311	Mohs micrographic technique, including removal of all gross tumor, surgical excision of tissue specimens, mapping, color coding of specimens, microscopic examination of specimens by the surgeon, and histopathologic preparation including routine stain(s) (eg, hematoxylin and eosin, toluidine blue), head, neck, hands, feet, genitalia, or any location with surgery directly involving muscle, cartilage, bone, tendon, major nerves, or vessels; first stage, up to 5 tissue blocks

HCPCS	Description

ICD-9	Description
140.0	Malignant neoplasm of upper lip vermilion border
140.1	Malignant neoplasm of lower lip vermilion border
140.9	Malignant neoplasm of lip unspecified vermilion border
172.0	Malignant melanoma of skin of lip

172.1	Malignant melanoma of skin of eyelid, including canthus
172.2	Malignant melanoma of skin of ear and external auditory canal
172.3	Malignant melanoma of skin of other and unspecified parts of face
172.4	Malignant melanoma of skin of scalp and neck
172.5	Malignant melanoma of skin of trunk, except scrotum
172.8	Malignant melanoma of other specified sites of skin
172.9	Melanoma of skin, site unspecified
173.0	Other malignant neoplasm of skin of lip
173.1	Other malignant neoplasm of skin of eyelid, including canthus
173.2	Other malignant neoplasm of skin of ear and external auditory canal
173.3	Other malignant neoplasm of skin of other and unspecified parts of face
173.4	Other malignant neoplasm of scalp and skin of neck
173.5	Other malignant neoplasm of skin of trunk, except scrotum
173.8	Other malignant neoplasm of other specified sites of skin
173.9	Other malignant neoplasm of skin, site unspecified
184.1-184.8	Malignant neoplasm of labia majora - malignant neoplasm of other specified sites of female genital organs
187.1-187.4	Malignant neoplasm of prepuce - malignant neoplasm of penis part unspecified
187.7	Malignant neoplasm of scrotum
187.9	Malignant neoplasm of other specified sites of male genital organs
209.31	Merkel cell carcinoma of the face
209.32	Merkel cell carcinoma of the scalp and neck
209.36	Merkel cell carcinoma of other sites
216.0	Benign neoplasm of skin of lip
216.1	Benign neoplasm of eyelid, including canthus
216.2	Benign neoplasm of ear and external auditory canal
216.3	Benign neoplasm of skin of other and unspecified parts of face
216.4	Benign neoplasm of scalp and skin of neck
216.5	Benign neoplasm of skin of trunk, except scrotum
216.8	Benign neoplasm of other specified sites of skin
216.9	Benign neoplasm of skin, site unspecified
232.0	Carcinoma in situ of skin of lip
232.1	Carcinoma in situ of eyelid, including canthus
232.2	Carcinoma in situ of skin of ear and external auditory canal
232.3	Carcinoma in situ of skin of other and unspecified parts of face
232.4	Carcinoma in situ of scalp and skin of neck
232.8	Carcinoma in situ of other specified sites of skin
232.9	Carcinoma in situ of skin, site unspecified
757.33	Congenital pigmentary anomalies of skin

ICD-10	**Description**
C00.0	Malignant neoplasm of external upper lip
C00.1	Malignant neoplasm of external lower lip

C00.2	Malignant neoplasm of external lip, unspecified
C4A.0	Merkel cell carcinoma of lip
C4A.10	Merkel cell carcinoma of unspecified eyelid, including canthus
C4A.20	Merkel cell carcinoma of unspecified ear and external auricular canal
C4A.30	Merkel cell carcinoma of unspecified part of face
C4A.39	Merkel cell carcinoma of other parts of face
C4A.4	Merkel cell carcinoma of scalp and neck
C4A.8	Merkel cell carcinoma of overlapping sites
C48.9	Merkel cell carcinoma, unspecified
C43.0	Malignant melanoma of lip
C43.10	Malignant melanoma of unspecified eyelid, including canthus
C43.20	Malignant melanoma of unspecified ear and external auricular canal
C43.30	Malignant melanoma of unspecified part of face
C43.31	Malignant melanoma of nose
C43.39	Malignant melanoma of other parts of face
C43.4	Malignant melanoma of scalp and neck
C43.8	Malignant melanoma of overlapping sites of skin
C43.9	Malignant melanoma of skin, unspecified
C51.0	Malignant neoplasm of labium majus
C51.1	Malignant neoplasm of labium minus
C51.2	Malignant neoplasm of clitoris
C51.9	Malignant neoplasm of vulva, unspecified
C57.7	Malignant neoplasm of other specified female genital organs
C57.8	Malignant neoplasm of overlapping sites of female genital organs
C60.0	Malignant neoplasm of prepuce
C60.1	Malignant neoplasm of glans penis
C60.2	Malignant neoplasm of body of penis
C60.9	Malignant neoplasm of penis, unspecified
C63.2	Malignant neoplasm of scrotum
C63.9	Malignant neoplasm of male genital organ, unspecified
D03.0	Melanoma in situ of lip
D03.10	Melanoma in situ of unspecified eyelid, including canthus
D03.11	Melanoma in situ of right eyelid, including canthus
D03.12	Melanoma in situ of left eyelid, including canthus
D03.20	Melanoma in situ of unspecified ear and external auricular canal
D03.21	Melanoma in situ of right ear and external auricular canal
D03.22	Melanoma in situ of left ear and external auricular canal
D03.30	Melanoma in situ of unspecified part of face
D03.39	Melanoma in situ of other parts of face
D03.4	Melanoma in situ of scalp and neck
D03.51	Melanoma in situ of anal skin
D03.8	Melanoma in situ of other sites
D03.9	Melanoma in situ, unspecified
D04.0	Carcinoma in situ of skin of lip

D04.10	Carcinoma in situ of skin of unspecified eyelid, including canthus
D04.20	Carcinoma in situ of skin of unspecified ear and external auricular canal
D04.30	Carcinoma in situ of skin of unspecified part of face
D04.39	Carcinoma in situ of skin of other parts of face
D04.4	Carcinoma in situ of skin of scalp and neck
D04.8	Carcinoma in situ of skin of other sites
D04.9	Carcinoma in situ of skin, unspecified
D22.9	Melanocytic nevi, unspecified
D23.0	Other benign neoplasm of skin of lip
D23.10	Other benign neoplasm of skin of unspecified eyelid, including canthus
D23.20	Other benign neoplasm of skin of unspecified ear and external auricular canal
D23.30	Other benign neoplasm of skin of unspecified part of face
D23.39	Other benign neoplasm of skin of other parts of face
D23.40	Other benign neoplasm of skin of scalp and neck
D23.9	Other benign neoplasm of skin, unspecified
Q82.81	Xeroderma pigmentosum

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