

Basic Data Skin

| | | | |
|---------------|---|---|--|
| Reg.-No. | Not listed i | (Template certificate) i | |
| Centre | | | |
| Clinical site | | | |
| Contact | i | Date recorded | i |
| | | Date first certification | ----- i |
| | | Indicator year | 2022 |

| | |
|-----------------------------|---|
| Federal state / Country | |
| Tumour documentation system | XML-OncoBox i Not yet available |

| Invasive malignant melanomas i | SKIN i | | | | | | | | | | | | Uveal, conjunctival, mucosal ³⁾ i | not classifiable (e.g.: pTx) ⁴⁾ | Total | |
|--|---|------------------|-------------------|-------------------|-------------------|--------------------|--------------------|--------------------|--------------------|--------------------------------------|-------------------------|------------------|---|--|-------|--|
| | with primary tumour | | | | | | | | | | with no primary tumour | | | | | |
| | IA ¹⁾ | IB ¹⁾ | IIA ¹⁾ | IIB ¹⁾ | IIC ¹⁾ | IIIA ¹⁾ | IIIB ¹⁾ | IIIC ¹⁾ | IIID ¹⁾ | IV ¹⁾ | IIIB/IIIC ¹⁾ | IV ¹⁾ | | | | |
| 5. 2) a) Patients with primary disease (= patients with initial diagnosis malignant melanoma) | | | | | | | | | | | | | | | | 0 |
| b) Number of cases with primary disease (= in the calendar year further synchronous/metachronous diagnoses of malignant melanomas at a different location, no recurrence, no stage shift) | | | | | | | | | | | | | | | | 0 |
| 6. a) Patients with second/third melanoma at different location (= patient already diagnosed with a malignant melanoma in a previous calendar year. Now: second/third malignant melanoma at a different site). | | | | | | | | | | | | | | | | 0 |
| b) Number of cases with second/third melanoma (= in the calendar year further synchronous/metachronous diagnoses of malignant melanomas at a different location, no recurrence, no stage shift) | | | | | | | | | | | | | | | | 0 |
| 7. Patients with stage shift/recurrence (= patient already diagnosed with a malignant melanoma in a previous or in the current calendar year. Now: recurrence, stage shift including new remote metastasis) | | | | | | | | | | i | | | | i | | 0 i |

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Optional: 8. Patients with ongoing therapy (= patients with ongoing therapy who have not already been counted in the categories 5-7 for the calendar year, counted 1x/calendar year) | | | | | | | | | | | | | | | | | | 0 |
| Optional: 9. Patients in aftercare (= patients who are not undergoing therapy in aftercare who have not already been counted in the categories 5-7 for the calendar year, counted 1x/calendar year) | | | | | | | | | | | | | | | | | | 0 |
| Primary cases patients with malignant melanoma =5a) + 6a) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Centre patients = 5a) + 6a) + 7) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| All patients with a malignant melanoma (with optional) = 5a) + 6a) + 7) + 8 + 9) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

| | |
|--|----------------------------|
| | Total primary cases |
| Epithelial tumours (excluding in situ) | |
| Cutaneous lymphomas and other rare malignant skin tumours (angiosarcoma, Merkel, DFSP, etc.) | |

| | |
|--------------------------------|---|
| Number of primary cases | 0 |
|--------------------------------|---|

The data collection form is based on the TNM - Classification of Malignant Tumours, 8th edition 2017 as well as the ICD classification ICD-10-GM 2021 (DIMDI) and the OPS classification OPS 2022 (DIMDI).

Processing remarks:

1) TNM 8 requirements:

| | | | |
|---|----------------------|--------------------|----|
| Stage 0 | pTis | N0 | M0 |
| Stage IA | pT1a, pT1b | N0 | M0 |
| Stage IB | pT2a | N0 | M0 |
| Stage IIA | pT2b, pT3a | N0 | M0 |
| Stage IIB | pT3b, pT4a | N0 | M0 |
| Stage IIC | pT4b | N0 | M0 |
| Stage IIIA | pT1a, pT1b, pT2a | N1a, N2a | M0 |
| Stage IIIB | pT1a, pT1b, pT2a | N1b, N1c, N2b | M0 |
| | pT2b, pT3a | N1, N2a, N2b | M0 |
| Stage IIIC | pT1a-b, pT2a-b, pT3a | N2c, N3 | M0 |
| | pT3b, pT4a | N1, N2, N3 | M0 |
| | pT4b | N1, N2 | M0 |
| Stage IIID | pT4b | N3 | M0 |
| Stage IV | Every T | Every N | M1 |
| Lymph node metastases with no clear primary tumour: | | | |
| Stage IIIB | T0 | N1b, N1c | M0 |
| Stage IIIC | T0 | N2b, N2c, N3b, N3c | M0 |

-
- 2) The table begins with 5 to avoid any confusion with tumour stages.
 - 3) Patients with a malignant uveal, conjunctival, choroidal or mucosal malignoma were only counted for column P. No double entries.
 - 4) Tx = tumour cannot be assessed.

Documentation examples at:

<https://www.onkozert.de/organ/haut/>

or

<https://www.krebsgesellschaft.de/zertdokumente.html>

Some of the fields are inter-dependent. Each line should, therefore, be completely processed from left to right and continuously from top to bottom. Grey fields must be processed. The processing of the Excel template should be done with Microsoft Office 2010 or one of the later versions. Microsoft Office 2007 can be used with some constraints (e.g. information buttons are not displayed). Earlier versions of Microsoft Office 2007 are not suitable for processing the Excel template. All numbers and texts must be entered manually (not using copy/paste function; the exception are data which are entered by OncoBox). Each change to the basic data leads to a change in the Data Sheet. The document "Specifications Data Quality" sets out the basic principles of data assessment as part of the audit process. In particular details are given on how to deal with indicators where the target value is not met (download from www.onkozert.de; section Instructions).

Indicator Sheet Skin

Centre

Reg.-No.

| | | |
|--------|------------|---------------|
| Centre | Not listed | Date recorded |
|--------|------------|---------------|

| IN | CR / GL | Indicator definition | Indicator target | Numerator | Population (= denominator) | Plausi unclear | Target value | Plausi unclear | Current value | | Data quality | Verification Centre | |
|-----|-----------------------|--|--|--|--|----------------|-----------------|----------------|---------------|---|--------------|---|---|
| | | | | | | | | | | | | Reasons / Cause (min. 30 characters / max. 500 characters) | Action taken/planned (if reasons are plausible, no action is required) |
| 1.1 | 1.1.3 | Epithelial tumours (exc. <i>in situ</i> , <i>inter alia</i> basal cell carcinoma, squamous cell carcinomas) | See target value | Primary cases (Def. see 1.1.3) | ---- | | ≥ 100 | | Number | 0 | Incomplete | | |
| 1.2 | | Invasive malignant melanomas (incl. malignant uveal, conjunctival, mucosal melanomas) | | | ---- | | ≥ 40 | | Number | 0 | Incomplete | | |
| 1.3 | | Cutaneous lymphoma and other rare, malignant skin tumours (angiosarcoma, Merkel cell carcinoma, DFSP, etc.) | | | ---- | | No target value | | Number | 0 | Incomplete | | |
| 1.4 | | Patients with stage shift / recurrence | ---- | Patients with stage shift / recurrence | ---- | | No target value | | Number | 0 | Incomplete | | |
| 2 | Guideline Melanoma QI | Melanoma: Discussion of cases | Presentation of all cases of the denominator in the tumour board | Patients of the denominator who were presented in the tumour board | Patients with stage shift / recurrence and primary cases with extracutaneous melanoma | | ≥ 95% | | Numerator | | Incomplete | | |
| | | | | | | | | Denominator | 0 | | | | |
| | | | | | | | | % | n.d. | | | | |
| 3 | | Melanoma: Therapy deviation from recommendation tumour board | Therapy deviation as rarely as possible from the tumour board recommendation | Patients of the denominator who were involved in a therapy deviation | Patients with stage shift / recurrence and primary cases with extracutaneous melanoma which were presented in the tumour board (= numerator Indicator 2) | ≤ 3% | ≤ 25% | | Numerator | | Incomplete | | |
| | | | | | | | | Denominator | 0 | | | | |
| | | | | | | | | % | n.d. | | | | |
| 4 | | Melanoma: Psycho-oncological care | Adequate rate of psycho-oncological care | Patients of the denominator that received psycho-oncological counselling in an inpatient or outpatient setting | Primary cases (= Indicator 1.2) + patients with stage shift / recurrence (=basic data R34) | < 5% | No target value | > 70% | Numerator | | Incomplete | | |
| | | | | | | | | Denominator | 0 | | | | |
| | | | | | | | | % | n.d. | | | | |
| 5 | Guideline Melanoma QI | Melanoma: Counselling social services | Adequate rate of counselling from social services | Patients of the denominator which received social services counselling in an inpatient or outpatient setting | Primary cases (= Indicator 1.2) + patients with stage shift / recurrence (=basic data R34) | < 15% | No target value | | Numerator | | Incomplete | | |
| | | | | | | | | Denominator | 0 | | | | |
| | | | | | | | | % | n.d. | | | | |
| 6 | 1.7.5 | Melanoma: Share of study patients | Inclusion of as many patients as possible in studies | Patients with a melanoma who were included in a study with an ethical vote | Primary cases with a melanoma stages III - IV | | ≥ 5% | > 80% | Numerator | | Incomplete | | |
| | | | | | | | | Denominator | | | | | |
| | | | | | | | | % | n.d. | | | | |
| 7 | | Sentinel node biopsy (SNB) | As frequently as possible, intra-operative documentation of the marked sentinel lymph node | SNB surgeries of the denominator with sentinel lymph node confirmed intraoperatively | SNB surgeries (multiple mentioning per patient possible) | | ≥ 90% | | Numerator | | Incomplete | | |
| | | | | | | | | Denominator | | | | | |
| | | | | | | | | % | n.d. | | | | |
| 8 | | Surgical interventions with safety margin defined in the guideline (= malignant melanomas, Merkel cell carcinomas, sarcomas and other rare malignant skin tumours) | See target value | Surgical interventions with safety margin in primary cases (= malignant melanomas, Merkel cell carcinomas, sarcomas and other rare malignant skin tumours) | ---- | | ≥ 30 | | Number | | Incomplete | | |
| | | | | | | | | | | | | | |
| | | | | | | | | | | | | | |
| 9 | | Surgical interventions with histological margin control (= epithelial tumours) | See target value | Surgical interventions with histological margin control in primary cases (= epithelial tumours) | ---- | | ≥ 100 | | Number | | Incomplete | | |
| | | | | | | | | | | | | | |
| | | | | | | | | | | | | | |

| | | | | | | | | | | | | | | | |
|----|-----------------------|--|---|---|---|-------|-----------------|--|--|-------------|------|------------|--|--|--|
| 10 | | Revision surgery after secondary bleeding | Lowest possible rate of revision surgeries after secondary bleeding | Revision surgery (OPS: 5-983) because of intra- or post-operative secondary bleeding (T81.0) after surgeries of the denominator | Sum numerators Indicators 8 + 9 | | ≤ 3% | | | Numerator | | Incomplete | | | |
| | | | | | | | | | | Denominator | 0 | | | | |
| | | | | | | | | | | % | n.d. | | | | |
| 11 | | Revision surgery in the case of secondary bleeding after SNB and LAD | Lowest possible rate of secondary bleeding requiring revision after SNB and LAD | Revision surgery (OPS: 5-893) because of post-operative secondary bleeding (T81.0) after surgeries of the denominator | SNB surgeries (= denominator indicator 7) + therapeutic LADs for stages III (multiple mentioning per patient possible) | | ≤ 3% | | | Numerator | | Incomplete | | | |
| | | | | | | | | | | Denominator | | | | | |
| | | | | | | | | | | % | n.d. | | | | |
| 12 | | Revision surgery after post-operative wound infections | Lowest possible rate of revision surgeries after post-surgical wound infections | Revision surgery (OPS: 5-893) because of post-operative wound infections (T81.4) after surgeries of the denominator | Sum numerators Indicators 8 + 9 | | ≤ 3% | | | Numerator | | Incomplete | | | |
| | | | | | | | | | | Denominator | 0 | | | | |
| | | | | | | | | | | % | n.d. | | | | |
| 13 | Guideline Melanoma QI | Melanoma: Sentinel node biopsy | As frequently as possible SNB in primary cases with cutaneous melanoma ≥ pT2a and with no sign of locoregional or remote metastasis | Primary cases of the denominator where SNB is carried out | Primary cases cutaneous melanoma with a tumour density ≥ pT2a and no sign of locoregional or remote metastasis (cN0, cM0) | | ≥ 80% | | | Numerator | | Incomplete | | | |
| | | | | | | | | | | Denominator | | | | | |
| | | | | | | | | | | % | n.d. | | | | |
| 14 | Guideline Melanoma QI | Melanoma: Safety margin (1 cm) in the case of radical excision | As frequently as possible a safety margin of 1 cm in the case of curative radical excision of a cutaneous melanoma with a tumour density of ≤ 2 mm | Primary cases of the denominator with radical excision with a safety margin of 1 cm | Primary cases cutaneous melanoma with a curative radical excision in case of a tumour density ≤ 2 mm | < 80% | No target value | | | Numerator | | Incomplete | | | |
| | | | | | | | | | | Denominator | | | | | |
| | | | | | | | | | | % | n.d. | | | | |
| 15 | Guideline Melanoma QI | Melanoma: Safety margin (2 cm) in the case of radical excision | As frequently as possible a safety margin of 2 cm in the case of curative radical excision of a cutaneous melanoma with a tumour density of > 2 mm | Primary cases of the denominator with radical excision with a safety margin of 2 cm | Primary cases cutaneous melanoma with a curative radical excision in case of a tumour density > 2 mm | < 80% | No target value | | | Numerator | | Incomplete | | | |
| | | | | | | | | | | Denominator | | | | | |
| | | | | | | | | | | % | n.d. | | | | |
| 16 | Guideline Melanoma QI | Melanoma: Lymphadenectomy | As frequently as possible therapeutic lymphadenectomy (LAD) in the case of clinical evidence of lymphoid metastasis and no evidence of distant metastases | Primary cases of the denominator with therapeutic LAD | Primary cases with melanoma with each pT and c/pN1b or c/pN2b or c/pN3b and M0 | < 80% | No target value | | | Numerator | | Incomplete | | | |
| | | | | | | | | | | Denominator | | | | | |
| | | | | | | | | | | % | n.d. | | | | |
| 17 | | Melanoma: Mutation analysis for BRAF | As frequently as possible mutation analysis for BRAF in the case of patients with cutaneous melanoma from stage III | Primary cases of the denominator with mutation analysis for BRAF | Primary cases with cutaneous melanoma from stage III | < 80% | No target value | | | Numerator | | Incomplete | | | |
| | | | | | | | | | | Denominator | 0 | | | | |
| | | | | | | | | | | % | n.d. | | | | |
| 18 | Guideline Melanoma QI | Melanoma: LDH determination | As frequently as possible LDH determination in the case of patients with melanoma developing into stage IV | Patients of the denominator with LDH determination | Primary cases and patients with a stage shift/recurrence with melanoma developing into stage IV | < 80% | No target value | | | Numerator | | Incomplete | | | |
| | | | | | | | | | | Denominator | 0 | | | | |
| | | | | | | | | | | % | n.d. | | | | |

Data quality indicators

| | | | | |
|----------------------|----------------------|--------------|--------------|--------------------|
| OK | Plausible | 0,00% (0) | 0,00% (0) | Processing quality |
| | Plausibility unclear | 0,00% (0) | | |
| Target value not met | | | 0,00% (0) | 0,00% (0) |
| Erroneous | Incorrect | 0,00% (0) | 100,00% (21) | |
| | Incomplete | 100,00% (21) | | |

Processing remarks:

The respective entry or change "number/numerator/denominator" (dotted fields) is only possible in the spreadsheet "Basic Data", carry-over is automatic. The numerator is always a subset of the denominator (exception: Indicator 6 - Melanoma: share of study patients)

1) Plausibility unclear

In comparison to the other Centres, the indicator value given is an unusual value. The classification "plausibility unclear" does not automatically mean a negative assessment. The indicator value is to be checked for correctness because of its unusual character. In individual cases a positive indicator value, when viewed in detail, may also depict a negative care situation (e.g. surplus care). The result of this check is to be explained in more detail by the Centre in the Data Sheet "Reasons/Cause". Where appropriate, specific actions should be defined and carried out in line with the procedure "Failure to meet the target value".

2) Target value not met

The relevant indicators are to be analysed. The result is to be documented in the spreadsheet Data Sheet (DS). The document "Specifications Data Quality" contains more detailed information about this.

3) Incomplete

If any indicators have the status "incomplete", then they are either to be supplied at a later stage or a clear statement is to be made about the possibility of future presentation ("incomplete indicators" always constitute a potential deviation).

Note:

For reasons of easy readability, the term "patient" expressly covers all gender attributions (female, male, other).