

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												Uveal, conjunctival, mucosal ³⁾ i	not classifiable (e.g.: pTx) ⁴⁾ i	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
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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

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- 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

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Centre	Not listed	Date recorded
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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).