
















Reg. No.	Not Listed 	(Template certificate) 	
Centre			
Location			
Contact		Date recorded	
		Date of initial certification	----- 
		Indicator year	2021

Country	
Tumour documentation system	XML-OncoBox Breast 
	No

Primary cases breast cancer Definition in accordance with CR 5.2.1 automatic carry-over "number / numerator / denominator" to the Indicator Sheet	Primary cases in men and women <sup>1)</sup>								Total <sup>7)</sup>
	Tis (= DCIS) (N0, M0)	T1 (N0, M0)	T2 (N0, M0)	T3 (N0, M0)	T4 (N0, M0)	N+ (every T incl. Tis/Tx 2), M0)	M1 (every N, every T incl. Tis/Tx)	not to be attributed	
<b>Primary cases</b> <sup>4)</sup>									
<b>Surgical primary cases</b>									
With BCS <sup>3)</sup>									
With mastectomies <sup>3)</sup>									
incl. surgical primary cases with neoadjuvant or preoperative systemic treatment*									
<b>Tumour location</b>	<b>Patients (women)</b>				<b>Patients (men)</b>				<b>Primary cases total <sup>7)</sup></b>
unilateral <sup>5)</sup>									
bilateral (synchronous) <sup>6)</sup>									
<b>Total</b>									

The Catalogue of Requirements is based on the TNM classification of malignant tumours, 8th edition 2017, ICD classification ICD-10-GM 2022 (DIMDI) and the OPS classification OPS 2021 (DIMDI).

\* The short-term (3 wk) preoperative administration of tamoxifen or AI to test endocrine sensitivity.

#### Processing remarks:

1) Details of the tumourstatus, which depending on therapy, may be pathological (pT, pN, pM) or clinical (cT, cN, cM). Examples:

- operated, non-neoadjuvant pretreated case: Details of pathological tumour status (pT)
- neoadjuvant pretreated and operated case or a non-operated case or a case with pT0 after biopsy and further resection: clinical tumour status (cT)

2) Primary tumour not detectable clinically or pathologically with positive lymph nodes and no primary metastasis

3) In the case of mastectomy with prior BCS in one breast, this is indicated as mastectomy. When correlating the T stages with type of surgical procedure (BCS / mastectomy), special features of neoadjuvant therapy are not taken into account (basis is pretherapeutic cT-status, not (y)pT).

4) Maximum 2 primary cases per patient can be counted (max. 1 case per breast). Other new tumours in an already diseased breast (even if this can be clearly demarcated histologically from the primary tumour) do not constitute a new / additional primary case.

5) Unilateral: Primary patient diagnosed with a breast cancer in one breast (left or right) in the indicator year

6) Bilateral: Primary patient diagnosed synchronously with breast cancers in both the left and right breasts that were jointly treated (in the special situation of cross-year diagnosis / therapy in December 2013 and January 2014, assignment of both cases and the patient to 2013).

7) The sum of primary cases stratified by tumour stages must correspond to the primary cases calculated from the patients with unilateral and bilateral carcinomas (fields column L / line 30 = column L / line 41)

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 the OncoBox). Each change to the basic data leads to a change in the Indicator Sheet. The document "Specifications Data Quality" contains the main foundations for data assessment as part of the audit process. In particular details are given of how to deal with indicators where the target value is not achieved (download from [www.onkozert.de](http://www.onkozert.de); section Instructions).

Annex CR Version K2.1 (Audit year 2023 / Indicator year 2022)  
**Indicator Sheet Breast**

Centre

Reg. No.  Date of initial certification

IN	CR/ GL	Indicator definition	Indicator target	Numerator	Population (= denominator)	Plausi- bility unclear	Target value	Plausi- bility unclear	Current value		Data quality
1		Post-operative tumour board	Post-operative presentation of as many primary cases as possible in the tumour board	Primary cases of the denominator presented in the postoperative tumour board	Surgical primary cases		≥ 95%		Numerator		Incomplete
									Denominator	0	
									%	n.d.	
2	1.2.2	Pretherapeutic tumour board	Adequate rate of pretherapeutic tumour board	Primary cases of the denominator presented in the pretherapeutic tumour board	Primary cases		≥ 40%		Numerator		Incomplete
									Denominator	0	
									%	n.d.	
3		Tumour board local recurrence/metastases	Presentation of all patients with 1st local recurrence and/or 1st distant metastasis in the tumour board	Patients of the denominator presented in the tumour board	Patients with 1st (local) recurrence and/or with 1st remote metastasis (= indicator 14b) (without primary M1 pat.)	< 70%	No target value		Numerator		Incomplete
									Denominator		
									%	n.d.	
4	GL QI	Radiotherapy after BCS in the case of invasive breast cancer	Adequate rate of radiotherapy of primary cases with invasive breast cancer and BCS	Primary cases of the denominator in which radiotherapy was recommended	Primary cases with an invasive breast cancer and BCS (without primary M1 pat.)		≥ 90%		Numerator		Incomplete
									Denominator	0	
									%	n.d.	
									Numerator		

IN	CR/ GL	Indicator definition	Indicator target	Numerator	Population (= denominator)	Plausi- bility unclear	Target value	Plausi- bility unclear	Current value		Data quality
5		Radiotherapy after BCS in the case of DCIS	Adequate rate of radiotherapies of primary cases with DCIS and BCS	Primary cases of the denominator in which radiotherapy was recommended	Primary cases with DCIS and BCS	< 80%	No target value		Denominator		Incomplete
									%	n.d.	
6		Chemotherapy in the case of receptor positive and nodal positive result <sup>1</sup>	Chemotherapy of as many receptor positive and nodal positive primary cases as possible	Primary cases of the denominator for which chemotherapy was recommended	Primary cases with invasive breast cancer with receptor positive and nodal positive result (without primary M1 pat.)	< 60%			Numerator		Incomplete
									Denominator		
									%	n.d.	
7	GL QI	Endocrine therapy in the case of steroid receptor positive result <sup>1</sup>	Endocrine therapy for as many steroid receptor positive primary cases as possible	Primary cases of the denominator for which endocrine therapy was recommended	Primary cases with invasive breast cancer in the case of steroid rec. positive result (without primary M1 pat.)		≥ 95%		Numerator		Incomplete
									Denominator		
									%	n.d.	
8	GL QI	Trastuzumab therapy over 1 year in the case of HER-2 positive result	Trastuzumab therapy for 1 year for as many HER-2 positive primary cases as possible	Primary cases of the denominator for which trastuzumab therapy over 1 year was recommended	Primary cases with invasive breast carcinoma with HER-2 pos. result ≥ pT1c (in neoadj. pre-treated and in non-operated patients: ≥ cT1c) (without primary M1 patients)		≥ 95%		Numerator		Incomplete
									Denominator		
									%	n.d.	
9	GL QI	Endocrine therapy for metastasis	Endocrine therapy as first-line therapy for metastasis as often as possible	Patients of the denominator, who were started on endocrine based therapy in the metastasised stage as first-line therapy	Patients with steroid receptor positive and HER2-negative invasive breast cancer with 1st remote metastasis (incl. primary M1 pat.)		≥ 95%		Numerator		Incomplete
									Denominator		
									%	n.d.	
10		Psycho-oncological care (Consultation ≥ 25 min.)	Adequate rate of psycho-oncological care	Patients of the denominator who received psycho-oncological care in an inpatient or outpatient setting (duration of consultation ≥ 25 min.)	Primary case Patients (= indicator 14a) + Patients with new (local) recurrence and/or distant metastases (= indicator 14b) (without		< 15%	No target value	Numerator		Incomplete
									Denominator	0	

IN	CR/ GL	Indicator definition	Indicator target	Numerator	Population (= denominator)	Plausibility unclear	Target value	Plausibility unclear	Current value		Data quality
				(duration of consultation ≥ 20 min)	primary M1 pat., since already included in the primary cases)				%	n.d.	
11		Counselling social services	Adequate rate of counseling by social service	Patients of the denominator who received counselling by social services in an inpatient or outpatient setting	Primary case Patients (= indicator 14a) + Patients with new (local) recurrence and/or distant metastases (= indicator 14b) (without primary M1 pat., since already included in the primary cases)	< 50%	No target value		Numerator		Incomplete
									Denominator	0	
									%	n.d.	
12	1.7.5	Share of study patients	Inclusion of as many patients as possible in studies	Patients who were included in a study with an ethical vote	Primary cases		≥ 5%	> 65%	Numerator		Incomplete
									Denominator	0	
									%	n.d.	
13	GL QI	Pretherapeutic histological confirmation	Pretherapeutic histological confirmation as often as possible	Primary cases of the denominator with pretherapeutic histological diagnosis confirmation by punch or vacuum-assisted biopsy	Primary cases with initial surgery and histology of invasive breast cancer or DCIS		≥ 90%		Numerator		Incomplete
									Denominator	0	
									%	n.d.	
14a	1.2.0	Primary cases breast cancer	See target value	Primary cases	-----		≥ 100		Number	0	Incomplete
14b	1.2.0	Patients with 1st (local) recurrence and/or distant metastasis (without primary M1 patients)	-----	Patients with recent (local) recurrence and/or distant metastases (without primary M1 Pat.)	-----		No target value		Number	0	Incomplete

IN	CR/GL	Indicator definition	Indicator target	Numerator	Population (= denominator)	Plausibility unclear	Target value	Plausibility unclear	Current value		Data quality
15	5.2.12	Number of surgical procedures for R0 resection for BCS	R0 resection as often as possible in the 1st surgical procedure at BCS	Primary cases of the denominator with only one surgical procedure up to final surgical condition BCS	Surgical primary cases with BCS and R0	< 70%	No target value		Numerator		Incomplete
									Denominator		
									%	n.d.	
16	5.2.9	Breast-conserving procedure for pT1	70-90% BCS for primary cases with pT1	Primary cases of the denominator with BCS (final surgical condition)	Surgical primary cases with pT1 (incl. (y)pT1)		70 - 90%		Numerator		Incomplete
									Denominator		
									%	n.d.	
17		Mastectomies	Adequate rate of mastectomies	Primary cases of the denominator with mastectomies (final surgical condition)	Surgical primary cases	< 15%	No target value	> 40%	Numerator	0	Incomplete
									Denominator	0	
									%	n.d.	
18	LL QI	Lymph node removal in the case of DCIS	As rarely as possible lymph node removal in the case of DCIS	Primary cases of the denominator with axillary lymph node removal (primary axillary lymph node removal or sentinel lymph node removal)	Primary cases DCIS and completed surgical therapy and BCS		≤ 5%		Numerator		Incomplete
									Denominator		
									%	n.d.	
19	5.2.10	Determination of nodal status in the case of invasive breast cancer	Determination of nodal status in the case of invasive breast cancer	Primary cases of the denominator for which nodal status was determined	Surgical primary cases with invasive breast cancer (without primary M1)		≥ 95%		Numerator		Incomplete
									Denominator		
									%	n.d.	
20a	GL QI	Only sentinel lymphonodectomy (SLNE) for pN0	As often as possible only sentinel lymph node removal (SNB) for pN0	Primary cases of the denominator with only sentinel node biopsy	Female primary cases of invasive breast cancer and negative pN staging and without preoperative tumour-specific		≥ 80%		Numerator		Incomplete
									Denominator		

IN	CR/ GL	Indicator definition	Indicator target	Numerator	Population (= denominator)	Plausi- bility unclear	Target value	Plausi- bility unclear	Current value		Data quality
		(women)			therapy				%	n.d.	
20b	GL QI	Only sentinel lymphonodectomy (SLNE) for pN0 (men)	As often as possible only sentinel lymph node removal (SNB) for pN0	Primary cases of the denominator with only sentinel node biopsy	Male primary cases of invasive breast cancer and negative pN staging and without preoperative tumour-specific therapy		≥ 80%		Numerator		Incomplete
									Denominator		
									%	n.d.	
21	GL QI	Intraoperative sample radiography / sonography	As often as possible intraoperative sample x-ray / sonography after marking	Procedures of the denominator with intraoperative sample x-ray or with intraoperative sample sonography	Surgical procedures with preoperative wire marking guided by mammography or sonography		≥ 95%		Numerator		Incomplete
									Denominator		
									%	n.d.	
22	5.2.11	Revision surgeries	Rate of postoperative revision surgeries as low as possible	Primary cases of the denominator with revision surgeries as a consequence of postoperative complications (only surgical primary cases)	Surgical primary cases	< 0.01%	≤ 5%		Numerator		Incomplete
									Denominator	0	
									%	n.d.	
23	GL QI	Therapy of the axillary lymphatic drainage for pN1mi	Rate of axillary lymphatic drainage for micro-metastasis as low as possible	Primary cases of the denominator with therapy (axillary dissection or radiotherapy) of the axillary lymphatic drainage (only surgical primary cases)	Primary cases with invasive breast cancer, pN1mi without neoadj. chemotherapy		≤ 5%		Numerator		Incomplete
									Denominator		
									%	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% (25)	
	Incomplete	100,00% (25)		

### Processing remarks:

<sup>i</sup> IN	<sup>i</sup> CR/ GL	Indicator definition	Indicator target	Numerator	Population (= denominator)	Plausi- bility unclear	Target value	Plausi- bility unclear	<sup>i</sup> Current value	Data quality
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The respective entry or change of "Number / Numerator / Population" (dotted fields) can only be made in the spreadsheet "Basic Data", the data are then automatically transferred.

The numerator is always a subset of the denominator (exception: Indicator 12 - Share of study patients).

<sup>1</sup> The cases (ER/PgR; 1-9% positive nuclei) classified as having an "uncertain response to endocrine therapy" according to the S3 Guidelines are to be documented separately in the tumour documentation system (not relevant for the presentation of the Indicator Sheet).

#### 1) Plausibility unclear

In comparison to other centres, the Indicator value provided/obtained 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 present a negative care situation (e.g. oversupply). The result of this check is to be explained in more detail by the Centre in the Catalogue of Requirements in the column "Reasons/Cause". Where appropriate, specific actions should be defined and carried out in line with the procedure "Failure to meet the target value" for the purpose of improvement.

#### 2) Target value not met

The relevant Indicators are to be analysed. The result is to be documented in the data sheet "Indicators". The document "Specifications Data Quality" contains more detailed information about this.

#### 3) Incomplete

If any Indicators have the status "incomplete", then they are to be provided at a later stage or a clear statement is to be made about the possibility of presenting missing data in the future ("incomplete Indicators" always constitute a potential deviation).

#### **Note:**

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