FAQs

Catalogue of Requirements for the Breast Cancer Centres

of the German Cancer Society (*Deutsche Krebsgesellschaft* - DKG)

Chairs of the Certification Committee: Prof. Dr. J. Blohmer, Prof. Dr. A. Scharl

Within the framework of the certification procedure, questions regularly crop up which require an explanation of the Technical and Medical Requirements. This document contains answers to the questions which the centres can refer to when implementing, and the experts can refer to when assessing the Technical and Medical Requirements.

Version FAQ and Catalogue of Requirements (CR)

Version status FAQ: 27.11.2025

The FAQs in this document are continuously checked to ensure they are up to date and adapted in line with changes to the Technical and Medical Requirements.

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FAQs - Catalogue of Requirements - Breast

1.1 Structure of the network

Section.	Requirement	Explanatory remarks of the Breast Cancer Centre	
1.1.1.d	The following points must be regulated in the agreements with the main treatment partners: • Mandatory participation in the tumour conferences (with the exception of nuclear medicine) • Ensuring availability • Description of the standard operating procedures for treatment processes relevant to the Breast Cancer Centre with a special focus on the interfaces • Obligation to implement indicated guidelines (S3 Guideline as a basic requirement) • Description of cooperation on tumour documentation • Declaration of willingness to cooperate with internal/external audits • Undertaking to comply with the relevant criteria laid down in the Special Requirements for Breast Cancer Centres (*Fachliche Anforderungen an Brustkrebszentren* – FAB) and to provide the relevant data annually • Declaration of consent of the treatment partners to be publicly identified as part of the Breast Cancer Centre (e.g. on its website) • 24/7 reachability of main clinical cooperation partners i.e. emergency intervention: surgeon, radiologist (except cooperation MRI), medical oncology therapy (gynaecologist and/or internist), radiotherapist	FAQ (25.09.2017) 24-hour availability of the main clinical cooperation partners: must both the gynaecologist and the internist be available 24 hours a day for medical oncological therapy? Example A: The gynaecology department is responsible for the medical tumour therapy, the haematologist/oncologist only participates in the tumour conferences in an advisory capacity. Example B: Medical tumour therapy is the responsibility of both gynaecology and haematology/oncology. However, the haematologist/oncologist is a practising doctor, i.e. not a "clinical" main cooperation partner. Answer: Ad A) The requirement for 24-hour availability applies to the responsible specialist discipline, i.e. here: gynaecology. Ad B) If both treatment partners care for the same patients, an agreement must be made on site as to who fulfils the 24-hour availability requirement.	

1.2 Interdisciplinary cooperation

Section	Requirements	Explanatory remarks of the Breast Cancer Centre	
1.2.2c	Pre-therapeutic case reviews (…)		
	In addition, patients with a planned mastectomy should be presented at the preoperative tumour conference (see “Standard operating procedures for handling oncoplastic and reconstructive surgical procedures in certified Breast Cancer Centres” on this **link**).	FAQ (18.02.2019) Does the requirement refer only to primary cases or also to recurrences? Answer: Recurrences with planned mastectomy should also be presented pre-operatively. However, only primary cases presented can be recorded in the key figure "pre-therapeutic case discussions".	

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1.4 Psycho-oncology

Section	Requirements		
1.4.2b	Documentation and evaluation In order to identify the need for treatment, screening for psychosocial stress is recommended see Indictaor "Psycho-oncological distress screening") and the results is to be documented. The proportion of patients with excessive stress in the distress screening should be presented. Psycho-oncological counselling Psycho-oncological care, in particular for patients with excessive stress in the distress screening, must be presented.	FAQ (21.07.2016) Can on-site contact replace screening? Answer: No. In order to identify the need for treatment, it is necessary to carry out a **standardised** screening for psychological stress (see S3 guideline Psychooncology: e.g. Distress-Thermometer or HADS) and to document the result. FAQ (28.08.2023) How should the proportion of patients with excessive distress in distress screening and further psycho-oncological care be presented? Answer: The number of screened patients who have shown an excessive test should be described. The processes of psycho-oncological care should be described; the number of counselling sessions carried out should be recorded.	

1.6 Patient Participation

Section	Requirement		
1.6.6	Event for patients An information event for patients is to be staged by the Breast Cancer Centre at least once a year. If patient events are (co-)financed by industry, this fact including potential conflicts of interest of the speakers must be disclosed. The centre must rule out any direct influence on patients by industry representatives..	FAQ (12.09.2023) How can the centre prove the exclusion of direct influence by industry representatives? Answer: Proof can be provided, for example, via internal compliance rules or, alternatively, via a self-declaration by the centre. In this, the centre should provide information on free access to the event, excluding the industry exhibition/information stands and remarks on contact between industry representatives and patrons.	

1.7 Study management

Section	Requirements		
1.7.5. a 1.7.5. b	Proportion of study patients Initial certification: some patients must have already been recruited for studies After 1 year: at least 5% of primary cases Only patients recruited for studies with a vote by the ethics commission count as participants (non-interventional/diagnostic studies are also recognised).	FAQ (28.01.2022) Do patients with breast carcinoma who were enrolled in the HerediCaRe study count towards the breast cancer centre study quota? Answer: For the counting of HerediCaRe patients (proof of study participation required), an exclusive application of the checklist and referral of the patients to an FBREK centre is not sufficient.	

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1.7 Study management

Section	Requirements		
	All study patients can be counted when calculating the study rate (proportion of study patients in relation to all the Centre's primary cases). General preconditions for the definition of the study rate: • Patients can be counted once for each study. The relevant date is the date of patient consent. • Patients in palliative and adjuvant situations can be counted, no limitation as to stages. • Patients who are recruited for a number of studies in parallel can be counted more than once. • Study patients can be counted for two centres, provided that the sending centre itself conducts at least one study for patients from the breast cancer centre. If this counting method is chosen (optional), the centre must indicate how many patients are included in studies at its own centre, sent to other centres/clinics to participate in studies, and accepted from other centres/clinics to participate in studies. • Registry studies can be counted if an ethics vote and a study plan with a defined research question are available.	FAQ (10.02.2022) Can negatively screened study pat. be counted? Answer: Patients who have signed a consent form for screening for study participation can be counted for the numerator of the respective study indicator, even if study participation of the patients is not possible due to the results of screening examinations performed with special diagnostics (no routine diagnostics). FAQ (25.07.2022) May studies with ethics vote but without pat. consent - e.g., pat. surveys - be counted? Answer: No, these cannot be counted. FAQ (28.08.2023) Can patients referred to a Centre for Personalised Medicine (CPM) for the purpose of complex diagnostics, interdisciplinary consultation and individual therapy recommendations who participate in a study there be counted towards the study quota of the sending centre? Answer: Yes, in this case the study inclusion can be counted by both the sending centre and the CPM. The other requirements for study inclusion according to the survey form will apply.	

2.1 Consultation hours

Section	Requirements		
2.1.4	Familial Breast Cancer The process for applying the checklist to identify a possible hereditary predisposition to breast and/or ovarian cancer in patients must be documented. The further course of action for patients with a risk score ≥ 3 must also be outlined. The algorithm for informing patients and, if necessary, initiating genetic testing must be defined and must take into account the checklist and the designated centres. Cooperation with certified centres for Hereditary Breast and Ovarian Cancer (HBOC Centres) for counselling and genetic testing must be demonstrated in writing in accordance with the HBOC (Hereditary Breast and Ovarian Cancer) cooperation agreement of the vdek (=Association of substitute health insurance funds).	FAQ (25.09.2017) Is the checklist for the recording of hereditary burden to be used for every patient presenting at the consultation? Answer: The checklist should be used for the patients of the centre. These may not be all patients who present at the consultation. FAQ (17.08.2021) Does non-compliance with the requirement "Collaboration with certified centres for familial breast and ovarian cancer (FREBK centres) for counselling and genetic testing must be demonstrated." result in a deviation? Answer: If cooperation cannot be proven, the reasons must be explained in the audit. If the reasons are	

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2.1 Consultation hours

Section	Requirements		
	The check list to record a hereditary risk in patients with the disease (invasive breast cancer and DICS) can be downloaded on this link. If you encounter any contractual issues, please contact the office of the German Consortium for Familial Breast and Ovarian Cancer at dk-fbrek@uk-koeln.de.	comprehensible to the auditor (**e.g. distance**), no deviation is made. FAQ (12.09.2023) Is the contract with vdek compulsory? Answer: No. A written cooperation agreement "based on the vdek contract" means that the contents of the vdek contract are included in the cooperation agreement FAQ (22.08.2025) Check list for hereditary predisposition: Does the checklist need to be completed again in the event of a recurrence or metastasis? Answer: Yes, because the family history may have changed between the initial completion of the checklist and the recurrence/new distant metastasis, which may result in a different score.	
2.1.6	In the case of (special) breast consultation hours, the following services are to be guaranteed: • Mammogram Appointment within 48 hours; an assessment of the mammogram by a specialist must be available during the breast consultation hours (can also be done in cooperation with an external radiologist) • Mammasonography: on the same day as the breast consultation hours or within 48 hours together with the mammography and, if necessary, histological clarification; • Requirement for performance: proof of qualification in mammasonography (specialist knowledge in mammography [existing protection] or ultrasound agreement KBV (=The National Association of Statutory Health Insurance Physicians) or fulfilment of the requirements according to the ultrasound agreement) • Standardised diagnosis documentation according to the S3 Guideline (e.g. use of the US BI RADS classification) • The performance and documentation of sonography must be implemented in accordance with the requirements of the ultrasound agreement; • Sonography should be assessed in the context of complementary breast diagnostics • Biopsy for histology directly during the breast consultation hours or appointment within one week after the complete US and	FAQ (17.03.2019) How is compliance with the requirements of the ultrasound agreement verified? Answer: Fulfilment of the requirements according to the ultrasound agreement can be proven by: a) Analogous to §4: FA or doctor in further training for gynaecology and obstetrics or radiology + certificate of the trainer (according to §8 Ultrasound Agreement in the version applicable as of 01.01.2018) on the independent performance of ultrasound examinations under supervision + submission of 200 B-mode ultrasound scans of the mammary gland during the audit. or b) Analogous to §5: Specialist in gynaecology and obstetrics or radiology + at least 18 months of full-time or part-time work in a specialist field whose core area includes mammary sonography + submission of 200 B-mode ultrasound scans of the mammary gland during the audit. or c) Analogous to §6: Specialist in gynaecology and obstetrics or radiology + certificate of successful participation in basic, advanced and final course + submission of 200 B-mode sonographies of the mammary gland during the audit. Note OnkoZert: The FAQ for section 2.1.6 ("Fulfilment of the requirements according to the ultrasound agreement") is equally valid for section	

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2.1 Consultation hours

Section	Requirements		
	MG diagnostics; exception: stereotactic vacuum biopsy within 2 weeks	3.10 (Requirement for mammary sonography, 1st bullet point), in which this requirement is shown again.	

3 Radiology

Section	Requirements		
3.7.1	Specialist qualification mammogram assessment All “curative” (diagnostic) mammograms performed in the Centre must be assessed by at least one qualified specialist for radiology or, for the purpose of protecting existing standards, by a specialist for gynaecology and obstetrics with the additional designation “X-ray diagnosis of the breast [Model Specialty Training Regulations – MwbO, 28.06.2013]”. One of the following conditions must be met as proof of qualification: • Active participation as an expert in mammography screening with fulfilment of the corresponding requirements • Regular assessment of mammograms of at least 1000 patients a year or • Regular assessment of the mammograms of at least 500 patients/year and successful participation in the case collection review of the Association of Statutory Health Insurance Physicians (KV – *Kassenärztliche Vereinigung)* every 2 years (the requirement to achieve the minimum case number can be met through successful participation in external case collections (e.g. reference centres, DRG).	FAQ (17.08.2021) Can the mammograms assessed during the screening conferences also be counted as part of the 500 patients/year (3rd sub-item)? Answer: No, they cannot be counted. FAQ (12.09.2023) Counts for item 3) (regular assessment of mammograms of at least 500 patients/year (...) also duplicate findings? Answer: Double findings can be counted as long as a written report of the double findings is available FAQ (12.09.2023) The hospital radiology department does not have the relevant qualifications in accordance with CR 3.6, so a cooperation agreement has been concluded with a radiological practice. Do the radiologists in the practice who are qualified to perform mammography findings have to attend the tumour board? Or is it sufficient for the hospital radiologists to take part in the tumour board? Answer: The specialists who are qualified must take part in the tumour board.	
3.9	Pre-operative wire marking and minimally invasive interventions At least 25 minimally invasive intervention (sonographic, mammographic, MRI-guided labelling or biopsy) er physician (Radiology and/or Gynaecology) per year • If possible, the target lesion should be penetrated and not overcut by > 1 cm, • If the target lesion does not penetrate, the distance between the wire and the target should be < 1cm. • Deviation cases with resulting intraoperative problems should be documented and discussed in the regular quality circles.	FAQ (17.08.2021) Do all practitioners who perform mammographic and MRI markings have to fulfil the qualification requirements in chap. 3.6 (professional qualification mammography reporting)? Answer: Yes, they must meet the requirements.	

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4 Nuclear medicine

Section	Requirements		
4.5	Documentation of detection rate The proportion of sentinel lymph nodes detected in relation to the examinations conducted: Using a sentinel node biopsy probe ≥ 90% Using sentinel node scintigraphy (optional, if it is possible to perform) ≥ 90% The detection rate is once a year to assessed and in case of undercutting to be discussed in an interdisciplinary setting.Other types of labelling (SPIO (LoE 2a, EG B, AGO +), indocyanine green (ICG) (LoE 2a, EG B, AGO +)) instead of Technetium are possible if the detection rate requirements are met and appropriate patient consent has been obtained and documented. (SPIO: limited MRI sensitivity in follow-up care; ICG: not authorised for imaging the SN in the axilla, off-label).	FAQ (17.08.2021) May sentinel node biopsies for vulvar carcinoma or malignant melanoma also be elected here? Answer: No, these cannot be counted, there is a restriction to breast surgery.	

5.2 Organ-specific surgical oncology

Section	Requirements		
5.2.4 a 5.2.4 b	Breast surgeons (for each clinical site): • At least 1 breast surgeon (= specialist) (is to be named with details of surgical experience the previous year) • If there is just 1 named surgeon, documented cover staff provisions must be in place • At least 50 breast surgeries a year (removal of an invasive tumour/DCIS, not restricted to primary cases) for each named surgeon	FAQ (25.09.2017) Which procedures can be counted as expertise for the surgeon? Answer: Removal of an inv. tumour/DCIS as part of primary/recurrent/secondary tumour surgery. Axillary dissections, sentinel node biopsies or post-resections alone cannot be counted (even if these were performed by a second surgeon).	
	For a second surgeon only those cases can be counted where he/she assists for the purposes of basic training. Each surgical procedure can only be attributed to one breast surgeon (situation: surgical procedure is carried out by 2 named breast surgeons. Exception: see section 5.2.7 Prolongation senior breast surgeon).	FAQ (25.09.2017) How are interventions for multifocal carcinomas to be counted? E.g. DCIS and inv. mamma ca. in one breast? Answer: Analogous to the primary case count, only one procedure per breast can be counted for the surgeon's expertise.	
5.2.6.	Basic training of new breast surgeons The basic training of a breast surgeon must be organised for each clinical site of a Centre and for every 100 primary cases. Breast surgeons undergoing basic training must document at least 20 surgical procedures a year (not as second surgeon).	FAQ (12.09.2023) Do all surgeons in training have to qualify as designated breast surgeons? Answer: Breast surgeons in training do not have to qualify as designated surgeons (e.g. rotating surgeons who only work at the Breast Cancer Centre for a limited period of time).	

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5.2 Organ-specific surgical oncology

Section	Requirements		
5.2.7	Approval of new breast surgeons Over the previous 3 years at least 60 surgical procedures (removal of an invasive tumour/DCIS, not restricted to primary cases) of breast cancer; documentation listed in tables including surgical reports.	FAQ (17.08.2021) Is a breast surgeon allowed to operate **on their own** after being relicensed? I.e. in the window of time between the 60th training intervention and first reaching the 50 mamma surgeries required annually for the designated mamma surgeon? Answer: Only if the 60 procedures required for accreditation have been provided without interruption the accredited breast surgeon can operate alone after reaching the 60 procedures (if this is not the case, e.g. due to sick leave, then not). FAQ (17.08.2021) Is it correct that training assists are only possible once the surgeon is a designated breast surgeon (i.e. no training assists in the period between the 60th training procedure and reaching the 50 breast surgeries for the first time)? Or is he already allowed to perform assists when he has been approved as a new breast surgeon, i.e. has reached the 60th training intervention? Answer: Only designated breast surgeons may perform training assists. Licensing alone is not sufficient.	
5.2.8	Qualification of surgeons in the Breast Cancer Centre Description of the special qualification (basic training) of breast surgeons via curricula. • Ablative procedures, where applicable radical tumour surgery with removal of breast muscles • Axillary dissection (including sentinel node technique) • Successful handling of complications after surgical procedure • Reconstruction, reduction, corrective surgery • Breast-conserving therapeutic methods: sectoral resections, skin-sparing mastectomy, sub-cutaneous mastectomy (where appropriate, intramammary advanced flaps, oncoplastic surgical procedures down to autologous tissue transfer) • Removal of local recurrences, where appropriate with plastic dressing	FAQ (25.09.2017) Is it correct that breast surgeons in training must already perform reconstructive procedures in order to be able to demonstrate the range of methods described in Chapter 5.2.10 after completing their training? How is it to be proceeded with regard to the training of the surgeons if no reconstructive interventions are performed at a location of a multi-site Beast Cancer Centre? Answer: Not every surgeon must be able to perform all procedures. However, the centre must have all the procedures listed.	
5.2.9	Risk-reducing operations When risk-reducing surgeries are performed on the Breast Cancer Centre, they are to be performed by designated breast surgeons. An independent imaging check for residual glandular tissue must be performed after every risk-reducing breast operation. This must be	FAQ (23.07.2025) The following applies to Breast Cancer Centres outside Germany (if the plastic surgeons perform risk-reducing operations): An independent imaging check for residual glandular tissue must be carried out after every risk-	

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5.2 Organ-specific surgical oncology

Section	Requirements		
	documented and an algorithm presented on how to proceed if residual glandular tissue is detected.	reducing breast operation. This must be documented and an algorithm presented on how to proceed if residual glandular tissue is detected.	

8. Pathology

Section	Requirements	Explanatory remarks by the Cancer Centre
8.4	Specialist experience At least 100 routine histologies of breast cancer cases per year	FAQ (12.09.2023) Must a double finding be obligatory? Answer: No

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FAQs - Indicator Sheet Breast

Basic data - Columns A-C - Primary cases – there of surgical primary cases with neoadjuvant or preoperative systemic treatment

FAQ (25.09.2017)
Why is a differentiation made between neoadjuvant and preoperative systemic therapy?

Answer:
A differentiation is made in order to be able to meaningfully record primary M1 patients. "Preoperative" refers to primary M1 cases that have undergone surgery.

FAQ (17.08.2021)
In which tumour margins (old vs. new) should resection be performed according to NACT?

Answer:
Resection in the new tumour margins is possible if an R0 resection can be achieved.

Basic data - Columns D-L - Primary case counting

FAQ (14.07.2016)
Pat. has both DCIS and microinvasive carcinoma: which diagnosis is counted as primary?

Answer:
The microinvasive carcinoma because it determines the therapy. Both tumours must be in one breast.

FAQ (25.09.2017)
Does Paget's disease only count with associated DCIS or invasive carcinoma as a primary case or may Paget's disease of the nipple alone also be counted?

Answer:
Paget's disease alone (=intracutaneous DCIS) counts as a primary case.

FAQ (14.07.2016)
Does LCIS (lobular carcinoma in situ) count as a primary case?

Answer:
No.

FAQ (17.08.2021)
Does a malignant phylloid tumour count as a primary case?

Answer:
No, it does not count because it is not a breast carcinoma or DCIS but a malignancy of other histogenesis.

FAQ (17.08.2021)
Can patients who strive shortly after diagnosis, were not presented at the tumour conference and did not receive any therapy (including best supportive care) be counted as primary cases?

Answer
No, without presentation in the tumour conference or initiation of therapy, such as best supportive care, it is not possible to count them as primary cases.

FAQ (25.09.2017)
Can a recurrence of breast cancer in the same breast be counted as a new primary case?

Answer:

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No. The principle applies that a maximum of one primary case can be counted per breast. If another tumour occurs in the same breast, this cannot be counted as a new primary case in the data sheet, irrespective of the tumour biology, the localisation, the time interval, etc. See also primary case definition in the breast survey form and footnote 4) in the basic data (data sheet).

FAQ (08.08.2019)
Can pat. with recurrence of breast carcinoma in condition after breast carcinoma >10 years be counted as primary case?

Answer:
Patients with breast carcinoma in condition after breast carcinoma >10 years are not to be counted as primary cases. However, these patients are to be taken into account for the key figures case discussion in case of local recurrence/metastases, psycho-oncological care and social service counselling.

FAQ (08.08.2019)
Which tumour status (clinical or pathological) is to be used for case assignment if the invasive part has been completely punched out and only the DCIS is still detectable in the operating theatre?

Answer:
The assignment is made on the basis of the clinical tumour status (cT) (footnote 1 Basic data).

3	Tumour board local recurrence/metastases	Numerator	Patients of the denominator presented in the tumour board	FAQ (17.08.2021) How are local recurrence or distant metastasis counted? Response: The 1st local recurrence and/or the 1st distant metastasis in the current calendar year are counted.
		Denominator	'Patients with 1st (local) recurrence and/or with 1st remote metastasis (= indicator 14b) (without primary M1 pat.)	
		Target value	No target value	
7	Trastuzumab therapy over 1 year in the case of HER-2 positive result	Numerator	Primary cases of the denominator for which trastuzumab therapy over 1 year was recommended	FAQ (17.08.2021) Can primary cases for which therapy with T-DM1 (trade name "Kadcyla," consisting of trastuzumab and emtansine) was recommended also be included in the numerator? Answer: Yes, these can be taken into account.
		Denominator	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)	
		Target value	≥ 95%	
8	Endocrine therapy for metastasis	Numerator	Patients of the denominator, who were started on endocrine based therapy in the metastasised stage as first-line therapy	FAQ see next row
		Denominator	Patients with steroid receptor positive and HER2-negative invasive breast cancer with 1st remote metastasis (incl. primary M1 pat.)	
		Target value	≥ 95%	

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<table>
<tr><td>FAQs Indicator 8</td><td colspan="4">FAQ (18.02.2019)
May systemic combination therapies or secondary endocrine therapies be counted?

Answer:
No. What is counted is how often first-line endocrine therapy was given in the metastatic setting. Secondary endocrine therapies are not counted. A combination with other procedures (surgery, radiotherapy or other systemic therapies that are not chemotherapies) is possible.

FAQ (18.02.2019)
What does "endocrine-based therapy" mean?

Answer:
This means that other systemic therapies that are not chemotherapies can be given at the same time - if necessary (e.g. AK therapies or therapies with a CDK4/6 or mTOR inhibitor). Patients with prior or concurrent chemotherapy can still not be counted.

FAQ (25.072022)
How are pat. to be counted who no longer meet the defined expressions of the denominator due to a receptor conversion under metastasis?

Answer:
If the pat. no longer have the required characteristics of "hormone receptor positive" and "HER2 negative" at the time of 1st distant metastasis, they cannot be counted for the denominator

FAQ (12.09.2023)
Can patients with bilateral breast cancer and different tumour biology in the left and right breast be counted in the denominator Ex: left breast HR-positive and HER2-negative, right breast triple negative

Answer: No, they cannot be counted</td></tr>
<tr><td rowspan="3">17</td><td rowspan="3">Lymph node removal in the case of DCIS</td><td>Numerator</td><td>Primary cases of the denominator with axillary lymph node removal (primary axillary lymph node removal or sentinel lymph node removal)</td><td rowspan="3">FAQ (24.01.2024)
Which papillary neoplasms can be counted?

Answer:
Papillary lesions with the morphology codes 8504/2, 8509/2 and 8509/3 can be counted.</td></tr>
<tr><td>Denominator</td><td>Primary cases DCIS with completed surgical therapy and BCS</td></tr>
<tr><td>Target value</td><td>≤ 5%</td></tr>
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