EUROPEAN CANCER CENTRES

Deutsche Gesellschaft für Senologie

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: 28. January 2022

The FAQs in this document refer to the following documents which are now in force:

Catalogue of Requirements Breast	Version K1	25.10.2021
Indicator Sheet Breast	Version K1.1	25.10.2021

Overview of FAQs

Catalogue of Requirements

Section CR	Requirement		Last update
1.1 Structure of the network	1.1.1	24/7 reachability of main clinical cooperation partners	25.09.2017
1.2 Interdisciplinary cooperation	1.2.2	Pre-therapeutic case reviews	18.02.2019
1.4 Psycho-oncology	1.4.2	Psycho-oncology – Availability and access	21.07.2016
1.7 Study management	1.7.5	Proportion of study patients	28.01.2022
2.1 Consultation hours	2.1.4	Familial breast cancer	17.08.2021
2.1 Consultation hours	2.1.6	Qualification mammary sonography	17.03.2019
3 Radiology	3.6	Specialist qualification mammogram assessment	17.08.2021
	3.8	Pre-operative marking	17.08.2021
4 Nuclear medicine	4.5	Documentation of detection rate	17.08.2021
5.2 Organ-specific surgical therapy	5.2.4	Breast surgeons	25.09.2017
	5.2.7	Approval of new breast surgeons	17.08.2021
	5.2.8	Qualification of surgeons in the Breast Cancer Centre	25.09.2017
10 Tumour documentation/ outcome quality	10.4	Cooperation with the cancer registry	17.08.2021

Indicator sheet

Indicator		Last update
Basic data	Primary cases - thereof surgical primary cases with neoadjuvant or preoperative systemic treatment	17.08.2021
Basic data	Primary case count	17.08.2021
3	Tumour board local recurrence/metastases	17.08.2021
8	Trastuzumab therapy over 1 year in the case of HER-2 positive result	17.08.2021
9	Endocrine therapy for metastasis	18.02.2019
19	Determination of nodal status in the case of invasive breast cancer	25.09.2017
20a/20b	Only sentinel lymphonodectomy (SLNE) for pN0 (women/men)	14.07.2016
23	Therapy of the axillary lymphatic drainage for pN1mi	08.08.2019

FAQs - Catalogue of Requirements - Breast

1.1 Structure of the network

Section.	Requirement	Explanatory remarks of the Breast Cancer Centre	
	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	
1.2.2	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".	

1.4 Psycho-oncology

Section	Requirements	Explanatory remarks of the Breast Cancer Centre	
1.4.2	Psycho-oncology – Availability and access Every patient must have timely access to psycho-oncological counselling in the vicinity. The offer must be made in a low-threshold manner.		
	Documentation and evaluation In order to identify the need for treatment, screening for psychosocial stress is recommended (e.g. see the S3 Guideline Psycho-oncology) and the outcome is to be documented. As a rule, a record is to be kept of the number of patients who have taken advantage of psycho-oncological counselling as well as the frequency, length and topics discussed.	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.	

1.7 Study management

Section	Requirement	Explanatory remarks of the Breast Cancer Centre	
1.7.5	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). All study patients can be counted when calculating the study rate (proportion of study patients in relation to all the Centre's primary cases).	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.	
	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.		

2.1 Consultation hours

Section	Requirements	Explanatory remarks of the Breast Cancer Centre	
2.1.4	Familial breast cancer The algorithm for referral to genetic counselling must be defined and must take into account checklists and designated centres. Cooperation with counselling and genetic testing centres must be documented (if possible with certified centres for familial breast and ovarian cancer). The check list to record a hereditary risk (invasive breast cancer and DICS) can be downloaded on this **link**. .	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 comprehensible to the auditor (e.g. distance), no deviation is made.	
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) • Ultrasound examination of the breast on the same day as the breast consultation hours Requirement for performance: breast ultrasound: documentation for breast ultrasound of basic, advanced and final courses or licence of the Association of Statutory Health Insurance Physicians in line with the ultrasound agreement or fulfilment of the requirements in line with the ultrasound agreement • Standardised diagnosis documentation according to the S3 Guideline (e.g. use of the US BI RADS classification) • Biopsy for histology directly during the breast consultation hours or appointment within a week; exception: stereotactic vacuum biopsy within 2 weeks	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.	

2.1 Consultation hours

Section	Requirements	Explanatory remarks of the Breast Cancer Centre	
		Note OnkoZert: The FAQ for section 2.1.6 ("Fulfilment of the requirements according to the ultrasound agreement") is equally valid for section 3.10 (Requirement for mammary sonography, 1st bullet point), in which this requirement is shown again.	

3 Radiology

Section	Requirements	Explanatory remarks of the Breast Cancer Centre	
3.6	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 assessing at least 5000 screening mammograms a year and successful participation in the corresponding case collection review or • 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.	
3.8	Pre-operative marking At least 25 preoperative markings (sonographic, mammographic, MRI-guided) a year by each physician (radiology and/or gynaecology) responsible for marking	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.	

4 Nuclear medicine

Section	Requirements	Explanatory remarks of the Breast Cancer Centre	
4.5	Documentation of detection rate	FAQ (17.08.2021) May sentinel node biopsies for vulvar carcinoma or malignant melanoma also be elected here?	

4 Nuclear medicine

Section	Requirements	Explanatory remarks of the Breast Cancer Centre	
	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.	Answer: No, these cannot be counted, there is a restriction to breast surgery.	

5.2 Organ-specific surgical oncology

Section	Requirements	Explanatory remarks of the Breast Cancer Centre	
5.2.4	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.	
5.2.7	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	

5.2 Organ-specific surgical oncology

Section	Requirements	Explanatory remarks of the Breast Cancer Centre	
		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.	

10 Tumour documentation/outcome quality

Section	Requirements	Explanatory remarks of the Breast Cancer Centre	
10.4	Cooperation with the cancer registry • Cooperation with the competent 65c cancer registry is to be documented based on the cooperation agreement. **Link Tumorzentren.de.** • OncoBox is to be fed with data by the competent cancer registry. • The full data are to be made available to the cancer registry in an ongoing manner. • The presentation of the data sheet and outcome quality should be ensured via the cancer registry to the extent that this information is relevant for the cancer registry. • Parallel systems are to be avoided. • As long as the competent cancer registry is unable to meet the requirements imposed, the Breast Cancer Centre is to use additional or alternative solutions. The Centre is responsible in the event of a non-functioning external solution.	FAQ (17.08.2021) Is a cooperation agreement mandatory even if cooperation with the 65c cancer registry is required by law? Answer: Yes. With the cooperation agreement, centres have the possibility to design and bindingly determine the cooperation in coordination with the cancer registry.	

----	Basic data	Columns A-C	Primary cases - thereof 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: 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	
8	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%	
9	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 (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:
		Denominator	Patients with steroid receptor positive and HER2-negative invasive breast cancer with 1st remote metastasis (incl. primary M1 pat.)	
		Target value	≥ 95%	

				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.
19	Determination of nodal status in the case of invasive breast cancer	Numerator	Primary cases of the denominator for which nodal status was determined	FAQ (25.09.2017) Will participation in the INSEMA study be taken into account if the target is not met? Answer: Participation in the INSEMA study is of course taken into account; no indications or deviations arise from the auditor if the target of the indicator is not met due to this.
		Denominator	Surgical primary cases with invasive breast cancer (without primary M1)	
		Target value	≥ 95%	
20a / 20b	Only sentinel lymphonodectomy (SLNE) for pN0 (women / men)	Numerator	Primary cases of the denominator with only sentinel node biopsy	FAQ (14.07.2016) Can patients be counted here who have had one or more non-SNs taken in addition to the SN? Answer: In principle, of course, more than 1 SC can be removed in the case of an SLNE. The decisive factor is whether the centre codes an SLNE or a conventional axillary dissection. If the latter, then no SLNE can be counted.
		Denominator	Female primary cases of invasive breast cancer and negative pN staging and without preoperative tumour-specific therapy / Male primary cases of invasive breast cancer and negative pN staging and without preoperative tumour-specific therapy	
		Target value	≥ 80%	
23	Therapy of the axillary lymphatic drainage for pN1mi	Numerator	Primary cases of the denominator with therapy (axillary dissection or radiotherapy) of the axillary lymphatic drainage (only surgical primary cases)	FAQ (08.08.2019) May primary cases with distant metastasis be included in the denominator? Answer: No, the denominator is limited to primary cases with only micrometastasis (without neoadj. chemotherapy).
		Denominator	Primary cases with invasive breast cancer, pN1mi without neoadj. chemotherapy	
		Target value	≤ 5%	