**Catalogue of Requirements for Breast Cancer Centres**

**of the German Cancer Society**

**Prepared by the DKG/DGS (German Cancer Society/German Society for Senology)**

**Certification Committee for Breast Cancer** **Centres**

**Chairmen** Prof. Dr. J. Blohmer, Prof. A. Scharl

**Members (in alphabetical order):**
ACO Working Group for Surgical Oncology

ADT Working Group of German Tumour Centres

AET Working Group for Genetic Tumour Diseases

AG ZBZ Working Group of Certified Breast Cancer Centres

AGO Working Group for Gynaecological Oncology

AGORS Working Group for Oncological Rehabilitation and Social Medicine

AGSMO Working Group for Supportive Measures in Oncology

AIO Working Group for Medical Oncology

APM Working Group for Palliative Medicine

AOP Working Group for Oncological Pathology

ARO Working Group for Radiological Oncology

ASO Working Group for Social Work in Oncology

BVDST National Association of German Radiotherapists

BNGO Association of Practice-based Gynaecological Oncologists

BNHO Professional Association of Haematologists and Oncologists

BVF Professional Association of Gynaecologists

BVP Professional Association of German Pathologists

CAO Surgical Working Group for Oncology

DeGIR German Society for Interventional Radiology and Minimal-invasive Therapy

DEGRO German Society for Radiation Oncology

DGCh German Society for Surgery

DGGG German Society for Gynaecology and Obstetrics

DGHO German Society for Haematology and Medical Oncology

DGN German Society for Nuclear Medicine

DGP German Society for Pathology

DGP German Society for Palliative Medicine

DGPRÄC German Society for Plastic, Reconstructive and Aesthetic Surgery

DGS German Society for Senology

DRG German Radiology Society

DVE German Association of Physiotherapists

DVSG German Association of Social Work in Health Care

ECIBC National representatives of the European Initiative on Breast Cancer

FSH National Association for Women’s Self-Help after Cancer

KOK Conference of Oncological Nursing and Paediatric Nursing Care

OPH Working Group for Oncological Pharmacology

PRIO Working Group for Prevention and Integrative Medicine in Oncology

PSO Working Group for Psychological Oncology

Mammogram screening

Experts

Committee “Gynaecological Cancer Centres”

S3 Guideline Breast Cancer

**Effective as of 25 October 2021**

This Catalogue of Requirements (CR) is binding for all audits conducted from 1 January 2022. The changes made to the version valid in audit year 2021 are highlighted in “green” in this updated version.

The following were incorporated:

* Interdisciplinary S3 Guideline for the Diagnosis, Therapy and Aftercare of Breast Cancer

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

Important notice: These translations are provided for your convenience only. In the event of any discrepancy or divergence of interpretation, the German text shall prevail.

**Information on the Breast Cancer Centre**

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| Breast Cancer Centre (BCC) |  |
| Director of the Breast Cancer Centre |  |
| Coordinator of the Centre |  |

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|  |  |  | This CoRapplies to |
|  |  |  |  |  |  |
| Clinical site 1 (hospital/place) |  |  |  |  |  |
|  |  |  |  |  |  |
| Clinical site 2 (hospital/place) |  |  |  |  |  |
| only for cooperating BCC |  |  |  |  |  |

**QM system certification**

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| --- | --- | --- | --- | --- |
| QM system certification |  | yes |  | no |

**Network/main cooperation partners**

The (main) cooperation partners of Breast Cancer Centres are registered in a master data sheet with the certification agency OnkoZert. All information about this registration is published on [www.oncomap.de](http://www.oncomap.de). The Centre is obliged to report all new and also all no longer valid cooperations. Any other updates (e.g. changes to management, contact data.) must be indicated in the corrected master data sheet in the run-up to the annual surveillance audit. The master data sheet for the registration of cooperation partners can be obtained from OnkoZert.

**Compilation/Updating**

The electronically generated Catalogue of Requirements is the basis for the certification of the Breast Cancer Centre. The details provided here have been checked for correctness and completeness.

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| The data on outcome quality refer to calendar year |  |

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| The questionnaire was compiled/updated on  |  |

**Contents**

1. General information on the Breast Cancer Centre
	1. Structure of the network
	2. Interdisciplinary cooperation
	3. Cooperation with referring physicians and providers of aftercare treatment
	4. Psycho-oncology
	5. Social work and rehabilitation
	6. Patient participation
	7. Study management
	8. Nursing care
	9. General service areas (pharmacy, nutritional counselling, speech therapy…)
2. Organ-specific diagnostics
	1. Consultation hours
	2. Diagnostics
3. Radiology
4. Nuclear medicine
5. Surgical oncology
	1. Multiple organ surgical therapy
	2. Organ-specific surgical therapy
6. Medical/internal oncology
	1. Haematology and oncology
	2. Organ-specific medical oncology therapy
7. Radio-oncology
8. Pathology
9. Palliative and hospice care
10. Tumour documentation/outcome quality

Annex: Data Sheet (Excel template)

**1 General information on the Breast Cancer Centre**

| * 1. **Structure of the network**
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| Section | Requirements | Explanatory remarks by the Breast Cancer Centre |  |
| 1.1.1 | Written agreements (cooperation contracts) are to be entered into with each of the main treatment partners. The agreements are to be reviewed annually by the Breast Cancer Centre to ensure that they are up-to-date. The BCC must be located adjacent to a department that provides hospital beds for inpatient treatment. |  |  |
|  | This is not necessary if the Centre is run by/located at only one clinical site. This does not, however, affect the obligation to define relevant standard operating procedures and to put in place any other necessary rules. This can, for example, be covered in a general manual. |  |  |
|  | The main cooperation partners are: surgeon, gynaecological oncologist, radiologist (with the exception of cooperating radiological units that only provide services for the Breast Cancer Centre in conjunction with breast MRIs), pathologist, medical oncologist, radiotherapist and specialist in nuclear medicine. |  |  |
|  | The following points must be regulated in the agreements with the main treatment partners:* Mandatory participation in the tumour boards (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

Colour legend: Change compared to version as of 23.08.2019 |  |  |
| 1.1.2 | Agreements with other treatment partners:Written agreements in which the willingness to engage in cooperation is confirmed are to be entered into with the following treatment partners:* Psycho-oncology
* Social services
* Self-help
* Genetic counselling Gene analysis, family medical history (BRCA-1, BRCA-2) and genetic counselling
* Physiotherapy
* Laboratory (with interlaboratory testing certificate)
* Hospice/palliative medicine
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|  | The following points can, for example, be covered in the agreements with the treatment partners:* Participation in further training measures and public relations work
* Description of cooperation and interfaces
* Type of reciprocal communication
* Upholding of confidentiality
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| 1.1.3 | Presentation of the Centre and contact personsThe overall structure of the Breast Cancer Centres is to be presented and accessible to the public (e.g. on the Internet). This includes providing the names of all of internal/external cooperation partners:* Name and address of the cooperation partner
* Contact with telephone and email address

In medical areas the responsibilities on the specialist level must be defined. |  |  |

| * 1. **Interdisciplinary cooperation**
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| Section | Requirements | Explanatory remarks by the Breast Cancer Centre |  |
| 1.2.0 | Number of primary cases of breast cancer a yearOn initial certification: ≥ 100 primary casesDefinition primary case:* Patients and not stays or surgical procedures
* One primary case is calculated for each breast.
* Histology report must be available.
* DCIS are counted as primary cases.
* Case can only be counted for 1 Centre. Therapy planning (interdisciplinary tumour board) and conduct of therapy by the Breast Cancer Centre (main therapy)
* The time of counting is the time of initial diagnosis.
* Breast cancer in men and primary M1 patients are counted as primary cases
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| 1.2.0 | Cooperating Breast Cancer Centres(consisting of several surgical sites)* Cooperating centres with more than 2 clinical sites are no longer authorised
* Initial certification/expansions into a cooperating centre are only possible if each clinical site documents ≥ 100 primary cases

Existing cooperationsExisting cooperations benefit from protection of the status quo subject to the following preconditions:* For each clinical site at least 50 primary cases
* Cooperating centre with 2 clinical sites with more than 150 primary cases
* Proof of a positive certification outcome in the audit report (= no deviation)
* Strict compliance with Q standards, joint treatment regimens
* Tried-and-tested cover staff provision for the breast surgeon

Cooperation between several clinical sites requires prior structural assessment (is also required for expansions and/or mergers). |  |  |
| 1.2.1a) | ScheduleThe tumour board must meet at least once a week.Web/online conference* If web-conferences are held, the sound and any material presented must be transmitted. It must be possible for each main cooperation partner to present its own documents and images.
* Telephone conferences with no image material are not permitted.
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| b) | Tumour board participantsParticipation in the tumour board on the specialist level is mandatory for the following specialties and must be documented in an attendance list:* Breast surgeon
* Radiologist
* Pathologist
* Radiotherapist
* Medical oncologist
* Gynaecological oncologist (when chemotherapy is administered by gynaecologist)

If the medical oncologist is unable to attend the conference, he may be represented by the gynaecological oncologist responsible for the chemotherapy (qualifications in line with section 6.2).Colour legend: Change compared to version as of 23.08.2019 |  |  |
|  | Associated specialties are to be included in the tumour boards as needed (e.g. psycho-oncology, nursing care, plastic surgery). |  |  |
|  | If several cooperation partners are identified by name for the specialty, then the attendance of one representative is sufficient, provided there is a formal exchange of information between them (e.g. via quality circles). |  |  |
|  | Regardless of this, every cooperation partner must attend a tumour board at least once a month. |  |  |
| c) | Tumour board preparationA written summary of the most important patient data should be compiled and sent to the participants beforehand. Prior assessment should be made of patients suited to participation in studies. |  |  |
| d) | Demonstration imagesPatient-related images (radiological/pathological) must be available during the tumour board and technical equipment suitable for presenting the images must be provided. |  |  |
| e) | Minutes tumour board* The result of the tumour board consists *inter alia* of a written, interdisciplinary treatment plan (“minutes tumour board”).
* The minutes of the tumour board must be part of the patient’s medical record and can, at the same time, serve as the medical report.
* The distribution of the treatment plan to the individual treatment partners (including the referring physician) is to be ensured.
* The “minutes of the tumour board” should be generated automatically by the tumour documentation system.
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| 1.2.2 | Pre-therapeutic case reviewsParticipants:Surgeon (gynaecologist and/or surgeon and/or plastic surgeon), radiologist, pathologist. Additional participants are to be invited depending on the indication (medical oncologist, gynaecological oncologist, radiotherapist, etc.) The cooperation partners for plastic surgery are to be invited.The screening conference can be recognised if the circle of participants is documented and corresponds to the required participants and the diagnostic reports for HR status, grading and HER2 status for invasive carcinomas are available. |  |  |
|  | If possible, every vacuum-assisted and punch biopsy should be discussed in the preoperative tumour board. At least, all vacuum-assisted and punch biopsies with BIRADS 4 and 5 and a B1- B4 pathology should be discussed. |  |  |
|  | In addition, patients with a planned mastectomy should be presented at the preoperative tumour board (see “Standard operating procedures for handling oncoplastic and reconstructive surgical procedures in certified Breast Cancer Centres” on this [link](https://www.krebsgesellschaft.de/zertdokumente.html?file=files/dkg/deutsche-krebsgesellschaft/content/pdf/Zertifizierung/Checklisten%20und%20Algorithmen/BZ_Verfahrensanweisung_rekonstrOP_170809.pdf)). |  |  |
| 1.2.3a) | Patients with (local) recurrence/distant metastasisAll patients of the Breast Cancer Centre with local recurrence/distant metastases are to be presented in the pre- and/or post-therapeutic tumour board. The presentation must include all cooperation partners of the BCC. For this indication the patient should be given information about surgical therapeutic options (resection) or interventional oncological procedures (regional or ablative). |  |  |
|  | In addition to the specialties cited in section 1.2.1 b), the following medical specialties should be included in decisions regarding therapy – depending on the location of the metastases (based on the S3 guideline): neurosurgeon, orthopaedic surgeon, general and visceral surgeon, thorax or trauma surgeon, palliative medicine |  |  |
|  | All tumour board meetings including their minutes are to be documented. |  |  |
| b) | Number of cases with local recurrence/newly diagnosed metastases presented in the tumour board. | Enter the value in the Data Sheet (Annex)  |  |
| c)new | Patients with neoadjuvant and surgical therapy must be presented postoperatively again in the tumor conference.Colour legend: Change compared to version as of 23.08.2019 |  |  |
| 1.2.4 | Therapy deviations* In principle, the treatment plans and/or recommendations of the tumour board are binding.
* Any deviations from the original therapy plan or divergences from the guidelines that are identified must be minuted and assessed. Measures to avoid such divergences are to be introduced, depending on the cause.
* If therapy is not initiated or is terminated prematurely at the patient's request (despite existing indication), this must also be documented.
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| 1.2.5 | Treatment planAn interdisciplinary treatment plan is to be drawn up for every patient. This is also required for patients whose cases were not presented in any tumour board. |  |  |
| 1.2.6 | Morbidity/mortality conferences (MM conferences)* The invited participants are the participants in the tumour board and referring physicians.
* The conference can be held on the same date as the tumour board or as events organised by the referring physicians.
* Patients with an unusual course of therapy or patients in aftercare are discussed.
* The number of discussed cases should amount to at least 5 % of the primary cases. Cases that develop positively and negatively are to be presented. Morbidity conferences are to be held at least twice a year.
* Minutes must be taken at the MM conferences.
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| * 1. **Cooperation with referring physicians and providers of aftercare treatment**
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| Section | Requirements | Explanatory remarks by the Breast Cancer Centre |  |
| 1.3.1 | Cooperating referring physiciansAn up-to-date list is to be kept of the main cooperating referring physicians.The referring physicians are to be informed about cooperation within the Breast Cancer Centre with regard to the following details: |  |  |
|  | Obligations of the Breast Cancer CentreReferring physicians have the right to participate in the tumour board when their patients are presented.Referring physicians are to be given an opportunity to present patients in cases of palliative care or recurrence. |  |  |
| 1.3.2 | Provision of documentsThe following documents are to be given to the referring physicians in a timely manner:Optional:* Surgical report
* Histology report

Mandatory:* Tumour board minutes/treatment plan
* Medical report/discharge letter
* Changes in therapy
 |  |  |
| 1.3.3 | Feedback systemA written standard operating procedure for recording, processing and feeding back the general and case-related concerns/questions/complications is to be put in place for the referring physicians. |  |  |
| 1.3.4 | Further trainingEvents for the exchange of experience and further training events are to be proposed once a year by the Breast Cancer Centre. Contents, results and participants are to be recorded. |  |  |
| 1.3.5 | Satisfaction survey of referring physicians* Every three years, a satisfaction survey of the referring physicians must be conducted. The results of this survey are to be assessed and analysed.
* The first survey of referring physicians’ satisfaction must be available for the first time at recertification (3 years after initial certification).
 |  |  |
|  | * The return rate should be at least 50%.
 |  |  |
| 1.3.6 | Contact personsReferring physicians must be provided with relevant details of the contact persons at the Breast Cancer Centre (e.g. telephone number, email address). They can be included in the information on cooperation partners that is mandatory. |  |  |
| 1.3.7 | Tumour documentation/follow-up* A description of cooperation with the referring physicians during aftercare is to be provided.
* The requirements for this are set out in section 10 “Tumour documentation”.
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| * 1. **Psycho-oncology**
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| Section | Requirements | Explanatory remarks by the Breast Cancer Centre |  |
| 1.4.1 | Psycho-oncology – qualification* ~~Psychologists~~ / ~~M. Sc.~~ qualified psychologists/ master in psychology, which qualifies for a scientifically recognised psychotherapy procedure or
* Medical doctor
* diploma/master´s degree in social pedagogy, which qualifies for a scientifically recognised psychotherapy

In each case with at least 1 additional training in psychotherapy: behavioural therapy, psychodynamic psychotherapy (analytical psychotherapy and psychotherapy based on depth psychology), systemic therapy, neuropsychological therapy (for psychological disorders caused by brain injuries), interpersonal therapy (IPT; for affective disorders and eating disorders), EMDR for the treatment of post-traumatic stress disorders, hypnotherapy for addictions and psychotherapeutic treatment for somatic disorders and specialty training in psycho-oncology (acknowledged by the German Cancer Society DKG).Licence to practice: At least 1 person in the psycho-oncology team of the network (inpatient or outpatient) must be licensed (psychological or medical psychotherapist)Protection of the status quo for all those who are currently approved and those who have started a DKG-recognised psycho-oncological further training course by 31.12.2019.Representatives of other psychosocial professional groups can be approved on presentation of the above-mentioned additional qualifications. For this, a case-by-case examination is required.Colour legend: Change compared to version as of 23.08.2019 |  |  |
|  | ~~The following courses are recognised as further training:~~ ~~“Further Training in Psycho-social Oncology” offered by the PSO or dapo or other adequate further training with > 100 teaching units. This can be documented in a special basic training curriculum.~~Colour legend: Change compared to version as of 23.08.2019 |  |  |
|  | ~~Representatives of other psychosocial professions (such as qualified social pedagogues, social workers etc.) can be accredited when they can provide proof of the additional qualifications cited above. In such cases an individual examination is required.~~~~The assumption of psycho-oncological tasks by social services, self-help groups or spiritual counsellors is insufficient.~~Colour legend: Change compared to version as of 23.08.2019 |  |  |
| 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 evaluationIn 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.  |   |  |
| 1.4.3 | Psycho-oncology – resourcesNeeds-basedat least 1 fully employed psycho-oncologist with the above-mentioned qualifications should be available to the Centre (to be designated by name).Colour legend: Change compared to version as of 23.08.2019 |  |  |
| 1.4.4 | Rooms A suitable room is to be made available for the psycho-oncological counselling of patients. |  |  |
| 1.4.5 | Organisational planIf psycho-oncological counselling is provided by external cooperation partners or for several clinical sites and clinics, the performance of tasks is to be laid down in an organisational plan that contains details *inter alia* of the availability of resources and local presence. |  |  |
| 1.4.6 | Psycho-oncology – tasksPsycho-oncological counselling is to be offered to patients at all stages of care (diagnosis, inpatient, post-inpatient).Goals and responsibilities of counselling:* Diagnostic clarification after positive screening
* Prevention/treatment of resulting psychosocial problems
* Activation of personal coping mechanisms
* Maintaining quality of life
* Consideration of social environment
* Organisation of subsequent outpatient care through cooperation with providers of outpatient psycho-oncological services
* Public relations work (event for patients or the like)
 |  |  |
|  | The following are also recommended:* Supervision, further training and hands-on training measures for staff
* Twice-yearly conceptual discussion between psycho-oncologists and nursing and medical staff
* Regular written and, if appropriate, oral feedback on psycho-oncological activities to the physician in charge of treatment (e.g. in a consultation report or documentation in the medical record).
* Participation in tumour boards as needed
* Close cooperation with social services
* Psycho-oncologists should present their work within the Centre at least twice a year.
 |  |  |
| 1.4.7 | Further training/specialty training/supervision* At least one dedicated further/specialty training course a year for each staff member (at least 1 day a year)
* External supervision is to be arranged regularly
 |  |  |

| * 1. **Social work and rehabilitation**
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| Section | Requirements | Explanatory remarks by the Breast Cancer Centre |  |
| 1.5.1 | Qualification social services * Social worker/social pedagogue
* Individual case studies according to the guidelines of the professional society are possible
* Additional qualification: Experience in the medical/oncological field

~~Rooms:~~~~A suitable room is to be made available for social counselling.~~~~Resources:~~~~At least 1 full-time position should be available for 400 counselling sessions of patients of the Centre (= primary cases, secondary metastasis, recurrence). The staff resources can be made available centrally. An organisation plan must be provided.~~Colour legend: Change compared to version as of 23.08.2019 |  |  |
| 1.5.2 | Social services - Resources:For patient counselling at least one full-time staff member is available in the Centre for 400 counselled patients (not cases) (= primary cases, secondary metastasis, recurrence). The staff resources can be grouped centrally. An organisation chart must be available.Colour legend: Change compared to version as of 23.08.2019 |  |  |
| 1.5.3~~1.5.2~~ | ~~Social services~~Offer and accessEach patient must be offered the option of counselling by social services at all stages of the disease in a timely manner and in the vicinity (documentation required). The offer must be made in a low-threshold manner.Colour legend: Change compared to version as of 23.08.2019 |  |  |
| 1.5.4~~1.5.3~~ | Scale of counsellingA record must be kept of the number of patients who receive counselling from the social services. |  |  |
| 1.5.5 | Premises:A suitable room must be made available for social service counselling.Colour legend: Change compared to version as of 23.08.2019 |  |  |
| 1.5.6~~1.5.4~~ | Topics of counselling:* Identification of social, economic and psychological crises
* Initiation of medical rehabilitation measures
* Advice on economic questions and social law (particularly with regard to medical/occupational rehabilitation, (also for a prophylactic mastectomy/ovariectomy in the case of mutation carriers), disability law, benefits in lieu of pay, retirement benefits etc.)
* Support for submitting applications
* Advice on outpatient and inpatient treatment options and referral to support schemes and specialised services
* Support for professional and social reintegration
* Cooperation with service funding agencies and service providers
* Intervention in crisis situations
 |  |  |
| 1.5.7~~1.5.5~~ | Additional tasks:* Public relations and networking
* Participation in ward conferences and tumour boards, supervision, further training
* Interdisciplinary cooperation, especially with physicians, nurses, physiotherapists, psycho-oncologists, spiritual counsellors, etc.
* Documentation of activities
 |  |  |
| 1.5.8~~1.5.6~~ | Further/specialty trainingAt least one dedicated further/specialty training course a year for each staff member (at least 1 day a year) |  |  |
| 1.5.9~~1.5.7~~ | Choice of rehabilitation centre for each patientIf there is an existing indication, the patient should be offered oncological rehabilitation in a consultation (see also 1.5.6) |  |  |

| * 1. **Patient participation**
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| Section | Requirements | Explanatory remarks by the Breast Cancer Centre |  |
| 1.6.1 | Patient surveys* All Centre patients must have the opportunity to participate in the patient survey.
* The survey is to be conducted at least every three years over a period of least three months.
 |  |  |
|  | * The return rate should be over 30% (if this rate is not reached, steps are to be taken)
 |  |  |
| 1.6.2 | Assessment of the patient survey* Responsibility for the assessment is to be laid down.
* The assessment is to refer to the patients of the Breast Cancer Centre.
* A documented assessment is to be undertaken.
* Actions are to be determined on the basis of the assessment.
 |  |  |
| 1.6.3 | Patient information (general)* The Breast Cancer Centre is to give a full presentation of itself and its treatment options (e.g. in a brochure, patient folder or on a website).
* The cooperation/treatment partners are to be named along with their contact details. The treatment options are to be described.
* The options presented are to cover: rehabilitation/follow-up treatment, self-help, treatment measures and alternatives.
 |  |  |
| 1.6.4 | Discharge consultationEach patient is given a discharge consultation in which the following topics are addressed and corresponding information is provided: disease status, therapy planning, aftercare, supportive measures (e.g. rehabilitation, medical aids stores, psycho-social programmes). The Information provided includes for example the Patient Guidelines Breast Cancer (*Patientenleitlinien Brustkrebs*): <http://leitlinienprogramm-onkologie.de/Brustkrebs.70.0.html> |  |  |
| 1.6.5 | Results of the tumour boardThe patient must be informed of the recommendations of the tumour board. The patient’s decision must be documented.  |  |  |
|  | Patient information (case-related):The patient should receive the following documents:* The tumour board minutes/treatment plan
* Medical report/discharge letter
* Aftercare plan/aftercare pass
* Study documentation (if applicable)
 |  |  |
| 1.6.6 | Event for patientsAn information event for patients is to be staged by the Breast Cancer Centre at least once a year. |  |  |
| 1.6.7 | Complaint managementAn official procedure for complaint management is in place. Patients are given feedback. Complaints are taken into account in the improvement process. |  |  |
| 1.6.8 | Self-help groupsThe self-help groups with which the Breast Cancer Centre actively cooperates are to be named. Written agreements are to be signed with the self-help groups and should be updated at least every 5 years. They should cover the following:* Access to self-help groups at all stages of therapy (first diagnosis, inpatient stay, chemotherapy, aftercare …)
* Publication of contact data of the self-help groups (e.g. in patient brochure, BCC website)
* Space for self-help groups to lay out their brochures
* Room regularly made available at the Breast Cancer Centre for discussions with patients
* Quality circle with the participation of representatives of psycho-oncology, self-help groups, social services, spiritual counselling, nursing care and medical staff
* Personal discussions between self-help groups and the Breast Cancer Centre with the goal of staging and mutually coordinating joint activities and events. Minutes are to be kept of the results of the discussions.
* A contact person (preferably from the nursing staff) must be identified by name for the self-help group.
* Participation of medical staff in events of the self-help groups
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| **1.7 Study management**  |
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| Section | Requirements | Explanatory remarks by the Breast Cancer Centre |  |
| 1.7.1 | StudiesAccess to studiesThe patients must have access to studies. The studies conducted at the Breast Cancer Centre are to be compiled in a list and this list should be available to the patients with a short description of the study. |  |  |
| 1.7.2 | Person in charge of studyThe physician in charge of the study is to be identified by name. |  |  |
|  | Study assistant/study nurse* A study assistant is to be named for each “unit conducting studies” in the “studies organigram”.
* The same assistant can act on behalf of a number of “units conducting studies” in parallel.
 |  |  |
| 1.7.3 | Study assistant – responsibilitiesThe spectrum of responsibilities is to be laid down in writing (e.g. in a job description) and can include the following:* Carrying out studies with the physician in charge of the study
* Care of patients during the study and in aftercare
* Organising and coordinating diagnostic and laboratory measures, sample shipment and study medication
* Collection and documentation of all data relevant to the study
* Preparing and overseeing audits and inspections by authorities
* The study assistant’s activities can be combined with other activities such as tumour documentation.
 |  |  |
| 1.7.4 | Standard operating procedures (SOPs): The standard operating procedures including responsibilities are to be laid down for the inclusion/initiation of studies. This includes for instance:* Selecting new studies including approval
* Internal announcement of new studies (updating list of study list, etc.)
* Study organisation (special characteristics, looking after study patients, documentation, etc.)
* Way in which study results are announced (e.g. staff members, patients)
 |  |  |
| 1.7.5 | Proportion of study patientsInitial certification: some patients must have already been recruited for studiesAfter 1 year: at least 5% of primary casesOnly 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). | Enter the value in the Data Sheet (Excel template)  |  |
|  | 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.
 |  |  |
| 1.7.6 | Cooperation with external institutionsCooperation on studies with external institutions must be set out in cooperation agreements. |  |  |

**List of studies**1)

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| --- | --- | --- |
| Responsiblecooperation partner 2) | Study name | Number of Centre patients recruited in 20223) |
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|  |  |  |
|  | Numerator: Indicator no. 12 “study rate” |  |

1) Processing of the list of studies is mandatory. It is not possible to simply refer to the Catalogue of Requirements of the Oncology Centre.

2) Responsible cooperation partner: Study unit/speciality unit managing the study (e.g. department for radio-oncology; joint haematology/oncology practice Dr Smith…). Name of cooperation partners has to be identical with name on [www.oncomap.de](http://www.oncomap.de) if listed there,

3) Only those study patients can be counted who are listed as Centre patients and who were included in 2019 in the study (no double counting of patients in more than 1 Centre).

Colour legend: Change compared to version as of 23.08.2019

| **1.8 Nursing care** |
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| Section | Requirements | Explanatory remarks by the Breast Cancer Centre |  |
| 1.8.1 | Specialist oncology nurses* At least one specialist oncology nurse must be actively involved in daily work at the Centre.
* Oncology nurses are to be identified by name.

In areas in which patients with breast cancer are treated, documentation is to be provided in each case of the implementation of the superordinate activities (see below) by a specialist oncology nurse. The assumption of tasks/cover staff are to be laid down in writing and documented. |  |  |
|  | The precondition for recognition as a specialist oncology nurse is * Specialty training specialist oncology nurse pursuant to the respective federal state regulations
* or the model of the federal state ordinance of the German Hospital Federation (*Deutsche Krankenhausgesellschaft* e.V. – DKG)
* or Advanced Practice Nurse (Master title) plus 2 years’ practical professional experience (equivalent to a full-time staff member) in the Breast Cancer Centre.
 |  |  |
| 1.8.2 | Patient-related tasks:* Specialist assessment of symptoms, side effects and stress
* Individual derivation of interventions from nursing standards
* Conduct and evaluation of nursing and therapeutic measures
* Identification of each patient’s counselling needs
* The need for specialist counselling is to be defined already in the nursing concept of the Breast Cancer Centre
* Ongoing information and counselling of patients (and their family members) over the entire course of the disease
* Conduct, coordination and documentation of structured counselling sessions and guidance of patients and family members; in line with the concept they may also be conducted by other specialist nurses with several years’ experience and oncological expertise.
* Participation in the tumour board ~~is desirable~~ (according to chapter 1.2).
* Initiation of and participation in multi-professional case reviews/nursing visits. The goal is to find solutions in complex care situations. The criteria for patient selection are to be laid down. For each year and Centre at least 12 case reviews/nursing visits are to be documented.

Superordinate activities:* A nursing concept is to be developed and implemented in which consideration is given to the organ-specific characteristics of oncological nursing in the Breast Cancer Centre.
* Drawing up of specialist in-house standards on the basis of (if possible) evidence-based guidelines (e.g. S3-LL Supportive).
* Offer of advice for colleagues/supervision.
* Networking of oncology nurses in a joint quality circle and participation in the quality circle of the Breast Cancer Centre.
* Interdisciplinary exchange with all professional groups involved in treatment.

Colour legend: Change compared to version as of 23.08.2019 |  |  |
| 1.8.3 | Introductory trainingThe introductory training of new members of staff is to be undertaken on the basis of a specialist oncological introductory training catalogue/plan with the participation of the specialist oncology nurse |  |  |
| 1.8.4 | Further/specialty trainingA training plan for nursing staff is to be submitted listing the planned training sessions for a period of one year.At least one dedicated further/specialty training course a year for each staff member (at least 1 day a year) who carries out quality-relevant activities for the Centre. |  |  |
| 1.8.5 | Staff qualifications - nursing staffAt least 1 quality circle attended by a specialist oncology nurse |  |  |

| * 1. **General service areas**
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|  | The Catalogues of Requirements of the Organ Cancer Centres and Oncology Centres have a uniform table of contents. For Breast Cancer Centres this section does not specify any Technical and Medical Requirements. |  |  |

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| 2 Organ-specific diagnostics |

| 2.1 Consultation hours |
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| Section | Requirements | Explanatory remarks by the Breast Cancer Centre |  |
| 2.1.1 | Information for/dialogue with patient in line with the participatory decision making model (PEF)Patients with primary breast cancerPatients with recurrence/distant metastasesInform patients of the diagnosis, explain the results, describe the various therapy options * The advantages of the suggested therapy
* The risks of adverse effects from the therapy along with treatments and/or possible long-term effects
* Possibility of participating in a clinical study
* Information regarding supportive measures
* Offer (and aid in) obtaining a second opinion
* The patient must be given sufficient time to make a decision
* Information must be provided according to the patient’s needs during the entire treatment process
* This requirement must be fulfilled in connection with section 1.6
* A general description is to be given of the way in which information is provided and the dialogue is organised. For each patient this is to be documented in medical reports and in minutes/records.
 |  |  |
| 2.1.2 | Breast consultation hoursOn what basis are the special consultation hours conducted (panel physician, personal authorisation, institute authorisation, hospital authorisation)? |  |  |
| 2.1.3 | The breast clinics for male and female patients must be held at least once a week and address the following topics:* Breast cancer detection
* Therapy planning
* Surgical advice (in the case of planned reconstruction)
* Aftercare (e.g. advice in the case of lymphoedema)
* Recording of family case history in relation to the familial breast cancer risk
* Counselling regarding benign breast disorders
* Counselling in cases of growth or developmental disorders of the breast
* Counselling, diagnosis and therapy in cases of inflammatory breast disease
* If it should prove useful, the topics can be addressed in special, independent consultation hours.
 |  |  |
| 2.1.4 | Familial breast cancerThe algorithm for referral to genetic counselling must be defined and must take into account checklists and designated centres ~~designated in the “Interdisciplinary S3 Guideline for the Diagnosis, Treatment and Aftercare of Breast Cancer”.~~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](https://www.krebsgesellschaft.de/zertdokumente.html?file=files/dkg/deutsche-krebsgesellschaft/content/pdf/Zertifizierung/Checklisten%20und%20Algorithmen/checkliste_erbliche_belastung_brust-a5-160330.xlsx).~~An algorithm and a standard cooperation agreement for cooperation with the centres designated in the S3 Guideline are available on this~~ [~~link~~](https://www.krebsgesellschaft.de/deutsche-krebsgesellschaft-wtrl/deutsche-krebsgesellschaft/zertifizierung/erhebungsboegen/organkrebszentren.html)~~.~~Colour legend: Change compared to version as of 23.08.2019 |  |  |
| 2.1.5 | Waiting time during the consultation hoursRequirement: < 60 min (target)How long is the wait for an appointmentRequirement: < 2 weeksThe waiting periods are to be recorded on a random basis and statistically assessed (Recommendation: assessment period 4 weeks a year). |  |  |
| 2.1.6 | In the case of (special) breast consultation hours, the following services are to be guaranteed:* MammogramAppointment 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
 |  |  |
| 2.1.7 | Waiting time for histology results (punch)Requirement: within 2 working days |  |  |
| 2.1.8 | Informing patient of diagnosis in a dignified manner* The diagnosis – especially a malignant one – is to be presented in person by a physician and in direct contact with the patient.
* Time until final diagnosis (presentation of the histology results to the patient):< 1 week
 |  |  |
| 2.1.9 | The waiting period between the results of the histological punch biopsy (presentation of diagnosis) and the date for surgery should leave sufficient time for reflection and counselling (at least 3 days) but not exceed 14 days. |  |  |
| 2.1.10 | Renewed presentation in the event of diagnostic or therapeutic side effects is to be organised. |  |  |
| 2.1.11 | The following standard operating procedures, which determine quality, are to be described along with details of responsibilities:* Breast diagnostics including presentation of diagnosis
* Therapy planning (prior to surgery)
* Pre-inpatient admission
* Diagnosis in cases of patients with local recurrence/distant metastases

Sufficient staffing resources must be available to carry out the standard operating procedures. |  |  |
| 2.1.12 | Mammogram screeningAt least 1 surgeon from the Centre should participate in the mammogram screening programme as a cooperating hospital physician Identification by name: |  |  |

| **2.2 Diagnostics** |
| --- |
| 2.2.1 | A standard operating procedure (SOP) must be available for conducting the staging examinations which takes into account the recommendations of the current S3-LL:* No staging for patients with UICC stage l without any signs of metastasis
* From UICC stage II with elevated risk (for example: HER2+, triple-negative), stages III and IV, staging (CT thorax/abdomen, scinti.) should be conducted.
* In the case of a clinical suspicion of metastases and for all patients with a planned decision on systemic chemotherapy/antibody therapy, imaging staging should be undertaken irrespective of the stage.
 |  |  |

| 3 Radiology |
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| Section | Requirements | Explanatory remarks by the Breast Cancer Centre |  |
| 3.1 | Specialists* At least 2 specialists with experience in breast diagnostics
* Specialists are to be identified by name

All of the specialists named for the Breast Cancer Centre must participate in the tumour board (preoperative, at least 12 x a year). |  |  |
| 3.2 | MTRA* At least 2 qualified medical-technical radiology assistants must be available and identified by name.
* Proof of qualification: specialist staff member for breast diagnostics in line with the German X-ray Society (DRG) or equivalent qualification as MTRA in mammogram screening with refresher course every 3 years
 |  |  |
| 3.3 | Medical Physics Expert (MPE) * In accordance with the Radiation Protection Ordinance (*Strahlenschutzverordnung* – StrlSchV) (sections 131, 132) (valid from 2019), the radiology unit must provide a medical physics expert (MPE) for the purpose of optimising the radiation protection of patients and staff in connection with CT examinations.
* Availability can be regulated via cooperation or service agreements.
* The routine presence of an MPE for all CT examinations is not necessary.
 |  |  |
| 3.4 | Mammogram equipment* The requirements set out in the Radiation Protection Ordinance (29.11.2018) and the agreement on quality assurance measures pursuant to section 135(2) book V of the Social Code (SGB V) on curative mammograms (1.10.2018) are to be met, if possible digitally.
 |  |  |
| 3.5 | Mammogram resultsMandatory indication of assessment categories 0-6 (in line with the BIRADS classification, 5th edition or section 12 Quality Assurance Measures in accordance with section 135 (2) SGB V on curative mammogram, as per 1 October 2018) and description of parenchyma composition (A-D, in line with the BIRADS classification, 5th edition)  |  |  |
| 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).

Colour legend: Change compared to version as of 23.08.2019 |  |  |
|  | If the curative mammogram is performed by a physician who does not fulfil the requirements cited above, supervision and a second assessment by a physician with the corresponding qualifications are required. |  |  |
| 3.7 | Double assessment in the BCCA double assessment of the mammograms of asymptomatic patients and patients in aftercare should be undertaken by the BCC.For these mammograms:* The standard operating procedure for second/double assessment is to be described.
* Discrepancies between assessments should be recorded and discussed in a quality circle
 |  |  |
| 3.8 | Pre-operative markingAt least 25 preoperative markings (sonographic, mammographic, MRI-guided) a year by each physician (radiology and/or gynaecology) responsible for markingColour legend: Change compared to version as of 23.08.2019 |  |  |
| 3.9 | Breast ultrasound* For breast diagnostics only ultrasound equipment with a frequency of ≥7.5 MHz is to be used
* Ultrasound equipment must comply with DIN EN 61157: 2007 + A1:2013
 |  |  |
| 3.10 | Requirement for performing breast ultrasound* Proof of a qualification in breast ultrasound (specialist in breast ultrasound [protection of existing standards], Ultrasound Agreement National Association of Statutory Health Insurance Physicians, or meeting the requirements of the ultrasound agreement)
* Standardised documentation of the diagnostic assessments in line with the S3 Guideline (e.g. use of US BI-RADS classification)
* The ultrasound is to be conducted in line with the requirements of the Ultrasound Agreement ink).
 |  |  |
| 3.11 | Stereotaxia* The procedure should preferably be digital and analogue only in exceptional cases
* Marking and biopsies must be possible and used
* Classical stereotaxy, a perforated plate or even tomosynthesis can be used for planning

Colour legend: Change compared to version as of 23.08.2019 |  |  |
| 3.12 | MRIAccess to MRI examinations is to be ensured. It must be ensured that there is an MRI intervention option. If an MRI cannot be performed directly at the Breast Cancer Centre, access must be regulated in a cooperation agreement.For the conduct of the MRI the recommendations of the Breast Imaging Working Group of the German Radiological Society are to be implemented (Updated Recommendations for MRI of the Breast. Fortschr Röntgenstr 2014; 186: 482–483).  |  |  |
| 3.13 | Percutaneous biopsies - number* Ultrasound biopsy
* Stereotactic biopsy
* MRI biopsy (optional)

(number for each treatment unit) |  |  |
| 3.14 | Image-guided marking - number* Mammogram
* Ultrasound
* MRI

(number for each treatment unit) |  |  |
| 3.15 | Image-guided biopsy Access to image-guided biopsies (CT and/or ultrasound-guided) is to be ensured in the case of suspected distant metastasis. |  |  |
| 3.16 | Standard operating procedures (SOPs) for radiologyThe imaging and marking SOPs must be described and assessed once a year to ensure they are up to date. |  |  |
| 3.17 | Further/specialty training* A training plan for physicians and other staff members (radiological technical assistants) is to be submitted in which the training planned for the period of one year is outlined.
* At least one dedicated further/specialty training course in breast diagnostics a year for each staff member (duration > 0.5 days) who carries out quality-relevant activities for the Breast Cancer Centre.
* The further/specialty training should be conducted by a specialist professional organisation (German Radiological Society) and/or DKG, DGS, DGGG (German Society of Obstetrics and Gynaecology) and others.
 |  |  |
| 3.18 | Quality circle* Quality circles are to be held at least four times a year at which specific breast topics are to be seen as one of the foci
* Scheduling e.g. in a training plan
* Minutes are to be taken during quality circles
 |  |  |

| 4 Nuclear medicine |
| --- |
| Section | Requirements | Explanatory remarks by the Breast Cancer Centre |  |
| 4.1 | Specialists* At least 1 specialist
* A qualified back-up plan is to be documented
* Qualified specialists are to be identified by name
* Physicians who have demonstrated specialist knowledge of nuclear medicine within the context of an individual examination are also recognised as specialists for nuclear medicine
 |  |  |
| 4.2 | MTA in nuclear medicine:At least 2 qualified MTAs must be available and identified by name. |  |  |
| 4.3 | Number of skeletal scintigraphies (multiple organ and not limited to oncology) per treatment unit)~~≥ 200~~≥ 400Colour legend: Change compared to version as of 23.08.2019 |  |  |
| 4.4 | Sentinel node standard operating proceduresPerformance, quality control and documentation of sentinel node biopsies and sentinel lymph node scintigraphies must adhere to the DGS consensus paper (Kuehn T. et al., Cancer 2005; 103:451–61).Sentinel node biopsy (scintigraphy)At initial certification: ≥ 20 a yearAfter 3 years: ≥ 30 a year(Expertise per treatment unit)Experience with injections, measurements using a probe, resection and pathological assessment is to be documented. |  |  |
| 4.5 | Documentation of detection rateThe proportion of sentinel lymph nodes detected in relation to the examinations conducted:Using a sentinel node biopsy probe~~At initial certification: ≥ 80%~~~~After 3 years:~~ ≥ 90%Using sentinel node scintigraphy (optional, if it is possible to perform)~~At initial certification: ≥ 80%~~~~After 3 years:~~ ≥ 90%The ~~clinical~~ detection rate is ~~to undergo regular quality control (at least once a year) by an interdisciplinary group (blue solution and radioactivity)~~ once a year to be assessed and in case of undercutting to be discussed in an interdisciplinary setting ~~(blue solution and radioactivity).~~Other types of labelling (SPIO, indocyanine green (ICG)) instead of Tc are possible if the detection rate requirements are met and appropriate patient consent has been obtained and documented.Colour legend: Change compared to version as of 23.08.2019 |  |  |
| 4.6 | Further/specialty training* A training plan for physicians and other staff members (radiology assistants) is to be submitted in which the training measures planned a period of one year are described.
* At least 1 dedicated further/specialty training course in breast diagnostics a year for each staff member (duration > 0.5 days) who carries out quality-relevant tasks for the Breast Cancer Centre.
* The further/speciality training should be conducted by a specific professional organisation and/or DKG, DGS, DGGG and others.
 |  |  |
| 4.7 | Quality circle* Quality circles that look at specific breast topics are to take place at least four times a year
* Scheduling for instance in a training plan
* Minutes are to be taken of quality circles
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| 5 Surgical oncology |

| 5.1 Multiple organ surgical therapy |
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| Section | Requirements | Explanatory remarks by the Breast Cancer Centre |  |
|  | The Catalogues of Requirements of the Organ Cancer Centres and Oncology Centres have a uniform table of contents. For Breast Cancer Centres this section does not specify any Technical and Medical Requirements.  |  |  |

| 5.2 Organ-specific surgical oncology |
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| Section | Requirements | Explanatory remarks by the Breast Cancer Centre |  |
| 5.2.1 | Inpatient careBeds must be available for breast patients. A patient’s stay in hospital should not be less than 4 days. |  |  |
| 5.2.2 | Operating theatres for breast surgery:number of operating theatres regularly used for breast surgery: at least 1 operating theatre  |  |  |
| 5.2.3 | Specialists for the Breast Cancer CentreAt least 2 specialists actively working for the Breast Cancer Centre in line with the list of posts (may also be breast surgeons in parallel). The specialists must be named. The director of a Breast Cancer Centre must be one of the main cooperation partners and must be a physician. |  |  |
| 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
 |  |  |
| 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). |  |  |
| 5.2.5 | In the case of more than 150 surgical procedures (removal of an invasive tumour/DCIS, not restricted to primary cases) in the previous 5 years, no annual proof is required any longer for recognition pursuant to CR 5.2.4.(Form to provide proof for initial application or prolongation via OnkoZert, [Link](https://www.onkozert.de/informationen/hinweise/)). |  |  |
| Prolongation senior breast surgeonIn the previous 5 years at least 150 surgical procedures (removal of an invasive tumour/DCIS, not restricted to primary cases). Surgical procedures as second surgeon (for the purpose of basic training or assisting a named breast surgeon) can be counted. |  |  |
| 5.2.6 | Basic training of new breast surgeonsThe 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). |  |  |
|  |  |
| 5.2.7 | Approval of new breast surgeonsOver 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. |  |  |
| 5.2.8 | Qualification of surgeons in the Breast Cancer CentreDescription 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 |  |  |
| 5.2.9new | Risk-reducing operations When risk-reducing surgeries are performed on the Breast Cancer Centre, they are to be performed by designated breast surgeons.Colour legend: Change compared to version as of 23.08.2019 |  |  |
| 5.2.10~~5.2.9~~ | How often is a breast-conserving procedure used?Breast-conserving surgical procedures for pT1 tumours:Requirement: 70 – 90%(An exceeding of the 90% value is to be viewed critically.) | Details in the Data Sheet(Excel template) |  |
| 5.2.11~~5.2.10~~ | Determination of nodal status* Nodal status should be determined by means of sentinel lymph node excision (SLNE)
* Once a decision has been taken to perform axillary dissection (see S3-LL),

≥ 10 lymph nodes should be excised |  |  |
| 5.2.12~~5.2.11~~ | Post-surgical complicationsRevision surgeries because of intra-operative or post-operative complications in own facilityRequirement: ≤ 5% |  |  |
| 5.2.13~~5.2.12~~ | Surgical therapy ~~(R0)~~ for BET ~~with~~:R0 with 1 surgical procedureR0 with 2 surgical proceduresR0 with ≥ 3 surgical proceduresNumber of R1 resections after completion of surgical therapy.Colour legend: Change compared to version as of 23.08.2019 |  |  |
| 5.2.14~~5.2.13~~ | Further/specialty training:* A training plan for medical and nursing staff is to be presented listing the planned training courses for a period of one year.
* At least 1 dedicated further/specialty training course a year for each staff member (at least 1 day a year) who carries out quality-relevant activities for the Breast Cancer Centre.
* The further/specialty training should be provided by a professional specialist organisation and/or DKG/DAS, DGS, DGGG and others.
 |  |  |
| 5.2.15~~5.2.14~~ | Quality circles* Quality circles that look at specific breast topics are to be held at least four times a year.
* Scheduling, e.g. in the training plan

Minutes are to be taken during quality circles |  |  |
|  |  |
| 5.2.16~~5.2.15~~ | Breast reconstruction* Description of responsibilities
* Internal: Details of surgeon(s)

External: Name/address of cooperation partner |  |  |
| 5.2.17~~5.2.16~~ | Contents cooperation agreement(if the breast reconstruction is covered through external cooperation)* The contents of the “Standard operating procedure (SOP) for handling oncoplastic and reconstructive surgical procedures in certified Breast Cancer Centres” are to be fully born in mind ([Link](https://www.krebsgesellschaft.de/zertdokumente.html?file=files/dkg/deutsche-krebsgesellschaft/content/pdf/Zertifizierung/Checklisten%20und%20Algorithmen/BZ_Verfahrensanweisung_rekonstrOP_170809.pdf))
* Binding compliance with the S3 Guideline, Annex 2 (Breast reconstruction)
* Available resources for the Breast Cancer Centre (ensuring prompt care for large ulcerated mammary carcinomas)
* Identification of operating theatre site(s)
* Standard operating procedure for decisions/agreements on therapy (link pre-operative tumour board), information/explanations for patients (in accordance with sections 1.6, 2.1), surgical aftercare

Exchange of information on cosmetic result from the angle of the patient |   |  |
| 5.2.18~~5.2.17~~ | Breast reconstruction proceduresThe Breast Cancer Centre is to offer the following breast reconstruction procedures:* Oncoplastic and glandular rotation flaps
* Implant reconstruction
* Expander reconstruction

Autologous tissue procedures in line with the S3 Guideline “Breast reconstruction with autologous tissue” (internal or via external cooperation agreement) are to be offeredAlternative reconstruction procedures must be explained to patients by a correspondingly qualified/experienced surgeon.For this, the patient should be given the “Information pamphlet Breast Reconstruction”. ([Link](https://www.krebsgesellschaft.de/zertdokumente.html?file=files/dkg/deutsche-krebsgesellschaft/content/pdf/Zertifizierung/Erhebungs-%20und%20Kennzahlenboegen/BZ_Infoblatt_Brustaufbau_Pat_170809.docx)). |   |  |
| 5.2.19new | Risk-reducing operations When risk-reducing surgeries are performed on the BCC, they must be performed by designated breast surgeons.Colour legend: Change compared to version as of 23.08.2019 |  |  |
| 5.2.20~~5.2.18~~ | QualificationThe surgeon’s qualification is to be documented by a curriculum or certificate (for more details, please refer to the standard operating procedure CR 5.2.22). |  |  |
| 5.2.21~~5.2.19~~ | General requirements* Indication, number and result (photo documentation) of the reconstructions performed are to be recorded for each procedure
* Treatment in accordance with the S3 Guidelines, Annex 2 (Breast reconstruction)
* Preparation of pre-operative and post-operative photo documentation (100%)
* Storage standards for all breast reconstruction procedures on offer
* The patient is to be informed of the advantages and disadvantages of breast reconstruction options and her decision is to be documented.
* Standard operating procedures are to be put in place for handling implants (choice of implant, supply of measurement prostheses, traceability and storage).
* Direct peri-operative care after reconstruction is to be ensured under the supervision of a specialist trained in the surgical procedure used.
* The 24-hour reachability of a surgeon with the corresponding expertise must be ensured.
 |  |  |

Table “Breast surgeons”

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Title, Name, First name | Senior breast surgeon 1)yes/no | Period 2)from … to | Number of surgical procedures 3)in line with CR 5.2.4 | Clinical site/Hospital 4) |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

1) Precondition senior breast surgeon (described in line with CR 5.2.5): positive qualification assessment by OnkoZert

2) Period normally the previous calendar year (= indicator year), deviations for instance in staff fluctuation, appointment of breast surgeons during the year, in the case of unclear fulfilment 1 breast surgeon can also be included twice for 2 periods (e.g. previous calendar year and current year up to date of submission CR)

3) For senior breast surgeons there is no requirement about annual expertise whereby the preconditions for the prolongation of the certificate after 5 years in line with CR 5.2.5 are to be taken into account. Notwithstanding this, details are required of surgical expertise for the previous calendar year to ensure transparency for the specialist or the committee that issues the certificate.

4) Relevant for multi-site centres or in the event that a surgeon regularly works in several clinical sites/hospitals as a surgeon (surgical expertise is to be indicated separately for each location/clinic)

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| 6 Medical oncology |

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| 6.1 Haematology and oncology |
| Section | Requirements | Explanatory remarks by the Breast Cancer Centre |  |
|  | The Catalogues of Requirements of Organ Cancer Centres and Oncology Centres have a uniform table of contents. For Breast Cancer Centres this section does not specify any Technical and Medical Requirements.  |  |  |

| 6.2 Organ-specific medical oncology therapy |
| --- |
| Section | Requirements | Explanatory remarks by the Breast Cancer Centre |  |
| 6.2.0 | Alternatively, the requirements to be met by medical oncology therapy can be set out in the “Catalogue of Requirements Outpatient Medical Oncology”. This is especially recommended when the medical oncology therapy unit is named as a cooperation partner (one-off, multiple organ presentation) for other certified Organ Cancer Centres. In this case, the “Catalogue of Requirements Outpatient Medical Oncology” is an annex to the Catalogue of Requirements” and is to be submitted with it.The Catalogue of Requirements “Outpatient Medical Oncology” can be downloaded at <http://www.onkozert.de/praxen_kooperationspartner.htm>. |  |  |
| 6.2.1 | Qualifications specialist * Specialist in internal medicine/haematology and oncology
* Specialist in gynaecology and obstetrics with focus designation “gynaecological oncology”

or * Specialist in gynaecology and obstetrics with additional designation “medicinal tumour therapy”

Mastery and execution of * endocrine treatment procedures
* immunological treatment procedures
* neoadjuvant/adjuvant therapy concepts
* palliative therapy concepts
* supportive therapy concepts
* treatment of side effects (e.g. concept for extravasation)
 |  |  |
|  | The name of a representative with the above-mentioned qualifications is to be given.The specialists designated here must monitor the medical oncology therapy. It is not possible to delegate the responsibilities to physicians who do not have the above-mentioned qualifications. |  |  |
| 6.2.2 | Specialist nurse /specialist medical assistantPrerequisites for the specialist nurse/specialist medical assistant responsible for administering chemotherapy:* Inpatient, day patient or clinical outpatient units in which medical oncological therapy is carried out by non-medical staff must be under the expert supervision of a specialist oncology nurse. Cooperating practices are not subject to this rule.
* 1 year’s professional experience in oncology
* At least 50 chemotherapy administrations (an estimate is possible for initial certification, documentation must be provided thereafter)
* Documentation of hands-on training in line with the recommendations of the Conference of Oncological Nursing and Paediatric Nursing Care (KOK) (KOK recommended action, administration of cytostatics by specialist nurses)
* Active involvement in the implementation of requirements for the emergency treatment and therapy of comorbid conditions and secondary pathologies.
* Counselling and/or education of the patients by nurses is to be documented.
 |  |  |
| 6.2.3 | Qualification treatment unit/partner* At least 50 medicinal tumour therapies (cytostatic therapies and/or targeted therapeutics and/or antibody therapies/immunotherapies, no hormonal therapies) a year for breast patients

or* At least 200 medicinal tumour therapies (cytostatic therapies and/or targeted therapeutics and/or antibody therapies/immunotherapies, no hormonal therapies) a year (for different types of tumour)
* Calculation method: ~~c~~systemic/cytostatic/targeted therapy for each patient (consisting of several cycles or administrations)
* When the number is not reached, expertise cannot be proven via cooperation
 |  |  |
| 6.2.4 | Outpatient/inpatient chemotherapyMedical oncology therapy must be available on both an outpatient and an inpatient basis (if necessary in cooperation, for this the qualitative and quantitative requirements of the chapter must be fulfilled).Colour legend: Change compared to version as of 23.08.2019 |  |  |
| 6.2.5 | Options to be offered* Cytostatic monotherapy
* Cytostatic combination therapy
* Immune and antibody therapy (including small molecules)
* Hormonal therapy, bisphosphonate therapy

General chemotherapy* Cytostatic workspace (in accordance with the legal guidelines), if necessary
* Professional waste disposal
* 24-hour on call service
 |  |  |
| 6.2.6 | Rooms for medical oncology therapy* Description of the rooms for outpatient intravenous tumour therapy
* Number of places (at least 2)
 |  |  |
| 6.2.7 | Description of standard operating procedures* All phases of the standard operating procedure for chemotherapy procedure and targeted therapies must be described (start, administration and end of therapy.
* Supportive measures In line with the Guideline, the identification of side effects and the laying down of measures are to be described for all therapy concepts and documented in detail for each patient.
 |  |  |
| 6.2.8 | Systemic therapy regimens* The drawing up of/changes to existing therapy regimens must be undertaken by means of regulated approval.
* The therapy regimens are to be protected from any unintended changes.
* The therapy regimens are comparable between the outpatient and inpatient units.
 |  |  |
|  | Therapy plans* All systemic therapy is to be planned on the basis of a therapy regimen.
* The therapy plan must be checked and approved.
 |  |  |
| 6.2.9 | Standards for comorbidities and secondary pathologiesStandards are to be drawn up for the treatment of comorbidities and secondary pathologies,especially for the treatment of extravasation, infections, anaemia, neutropenia, emesis and thromboembolic complications.  |  |  |
| 6.2.10 | Emergency treatmentAvailability of emergency equipment and a written action plan for emergencies  |  |  |
| 6.2.11 | Medicinal treatment in the metastasised situation* The standard operating procedures for treatment (diagnosis/therapy) of patients with local recurrences/metastases are to be described (presentation of the patient pathways).
* A regular assessment of the toxicity of the therapy is to be undertaken using selected and documented measurement parameters (symptoms, indicator metastasis or the like).
* An evaluation of the therapeutic effect is to be documented every 3 months for each patient.
 |  |  |
| 6.2.12a) | Pain management therapy* A pain management therapist must be available.
* The standard operating procedure for pain therapy (algorithm) is to be described.
* When this service is provided by a cooperation partner, a cooperation agreement is to be entered into.
 |  |  |
| b) | Supportive therapy* Description of the options for supportive therapy (description of the standard operating procedure/algorithm)
 |  |  |
| 6.2.13 | Information for/dialogue with the patient Adequate information is to be provided about diagnosis and therapy planning and an adequate dialogue is to be conducted. This includes *inter alia*:* Presentation of possible treatment concepts
* Offer of and aid in obtaining second opinions
* Discharge consultation as a standard procedure

A general description is to be given of the way in which information is provided and the dialogue organised. This is to be documented for each patient in medical reports and minutes/records. |  |  |
| 6.2.14 | Further/specialty training* A training plan for physicians, nurses and other staff members is to be presented listing the planned training courses for a period of one year.
* At least 1 dedicated further/specialty training course a year for each staff member (duration > 0.5 days a year) who carries out quality-relevant activities for the Breast Cancer Centre.
* The further/additional training should be provided by a professional specialist organisation and/or DKG, DGS, DGGG, DEGRO and others.
 |  |  |
| 6.2.15 | Quality circles* Quality circles that look at specific breast topics are to be held at least four times a year
* Scheduling e.g. in training plan
* Minutes of quality circles are to be taken.
 |  |  |

| 7 Radio-oncology |
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| Section | Requirements | Explanatory remarks by the Breast Cancer Centre |  |
| 7.0 | The Technical and Medical Requirements to be met by radio-oncology are summed up in the "Catalogue of Requirements Radio-Oncology" in a multiple organ manner. Independently of the number of Organ Cancer Centres / Modules, which work with a radio-oncology unit, this "Catalogue of Requirements Radio-Oncology" is only to be processed once and also only updated once for each audit year (goal: no multiple presentations or on-site inspections within one audit year). The "Catalogue of Requirements Radio-Oncology" is therefore an annex to this Catalogue of Requirements.Download multiple organ "Catalogue of Requirements Radio-Oncology" at [www.onkozert.de](http://www.onkozert.de/). |  |  |

| 8 Pathology |
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| Section | Requirements | Explanatory remarks by the Breast Cancer Centre |  |
| 8.0 | The Technical and Medical Requirements to be met by pathology are summed up in the "Catalogue of Requirements Pathology" in a multiple organ manner. Independently of the number of Organ Cancer Centres / Modules, which work with a pathology unit, this "Catalogue of Requirements Pathology" is only to be processed once and also only updated once for each audit year (goal: no multiple presentations or on-site inspections within one audit year). The "Catalogue of Requirements Pathology" is therefore an annex to this Catalogue of Requirements.Download multiple organ "Catalogue of Requirements Pathology" at [www.onkozert.de](http://www.onkozert.de/). |  |  |

| 9 Palliative care  |
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| Section | Requirements | Explanatory remarks by the Breast Cancer Centre |  |
| 9.1 | Palliative care* Documentation is to be provided of cooperation agreements with service providers offering specialist outpatient and inpatient palliative care and inpatient hospices.
* Regional concepts for the integration of palliative care are to be described on the basis of the treatment pathway for patients and family members from the S3 Guideline (Fig. 3, p. 174) along with the names of all persons involved.
* A physician with the additional designation palliative medicine must be available for consultations and, where applicable, tumour boards.
* The group of patients with incurable cancer is to be defined, for instance in the tumour board. They are to be informed in a timely manner about palliative medical support services (SOP) (S3 Guideline Palliative Medicine.
* Access to palliative medical care can be offered in parallel to tumour-specific treatment.
* The number of primary cases with incurable cancer is to be documented.
 |  |  |
| 9.2 | Supportive therapy and alleviation of symptoms in the palliative setting* The options for supportive/palliative inpatient therapy are to be described (SOP/algorithm).
* A pain management therapist must be available. The standard operating procedure for pain management therapy (algorithm) is to be described and confirmed using documented cases for the assessment period.
* Access to nutritional counselling and occupational therapy is to be described
* Access to psycho-oncological, psychosocial and pastoral is to be described.
* When provided by a cooperation partner, a cooperation agreement is to be entered into for the above-mentioned requirements.
 |  |  |

| 10 Tumour documentation/outcome quality  |
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| Section | Requirements | Explanatory remarks by the Breast Cancer Centre |  |
| 10.1 | Tumour documentation systemTumour documentation that contains the patient data for a period of at least 3 months must be in place at the time of initial certification. Name of the tumour documentation system in the cancer registry and/or Centre |  |  |
| 10.2 | Period covered by the dataThe full data are to be presented for the previous calendar year.  |  |  |
| 10.3 | Requirements to be met by the tumour documentationA data set must be used that is in line with the uniform basic oncological data set and its modules of the Working Group of German Tumour Centres (ADT) and the Association of Population-based Cancer Registries in Germany (GEKID).The Centre must ensure that the data are transferred in a timely manner to the competent cancer registry after completion of primary therapy. Any existing federal state laws for notification deadlines are to be taken into account. |  |  |
| 10.4 | Cooperation with the cancer registry* Cooperation with the competent 65c cancer registry is to be documented on the basis of the cooperation agreement.

[Link Tumorzentren.de](http://www.tumorzentren.de/tl_files/dokumente/Kooperationsvereinbarung%20ADT_DKG_07.07.2015%20.docx).* 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.
 |  |  |
| 10.5 | Documentation officerOne documentation officer is to be designated who bears responsibility for tumour documentation. Name/Function:The documentation officer has the following tasks:* Ensuring and monitoring the timely, complete, full and correct transfer and quality of the patient data of relevance for certification by all cooperation partners to the cancer registry
* Motivation to encourage trans-sectoral cooperation by participating speciality units in the cancer registry (pathology reports, radiotherapy and medicinal treatments)
* Ensuring and monitoring the timely, complete and correct recording of patient data
* Qualification and support for the staff involved in data collection
* Regular analysis of the evaluations particularly over the course of time
 |  |  |
| 10.6 | Provision of resourcesThe required staff capacity should be made available for the carrying out of documentation tasks and the collection of data, (e.g. by a cancer registry) (e.g. 0.5 full-time position for 200 primary cases and 0.1 full-time position for 200 aftercare cases) |  |  |
| 10.7 | The tumour documentation system must offer at least the following selection options:* Cohorts
* TNM classification or comparable classifications and prognosis factors
* Forms of therapy (surgical therapy, radiotherapy, hormonal therapy, immunotherapy, chemotherapy)
* Date of recurrence/metastasis
* Deaths
* Follow-up status (latest update)
 |  |  |
| 10.8 | Outcome quality indicatorsKaplan-Meier curves:* Overall survival (OAS) for all patients in subgroups according to pT categories, stages
* Metastasis-free survival for all patients and for subgroups
* Progression-free survival (PFS) or disease-free survival for all patients or disease-free survival for all patients and subgroups
* Local recurrence rate for all patients and for subgroups
* Post-progression survival (PPS)
* At the start all cohorts are to be grouped together (3 years). In the case of larger patient numbers and outcome numbers, several cohorts can be evaluated separately.
* A table with patient numbers and survival data is an integral part of every Kaplan-Meier curve.

Detailed organ-specific requirements are compiled in the Annex on matrix outcome quality. For special features of non-binding presentation see CR 10.11. |  |  |
| 10.9 | Data evaluation* The presentation of outcome quality (see previous point) must be possible for recertifications.
* The data in the tumour documentation system are to be evaluated and analysed at least once a year.
* If benchmarking/annual report is offered, the benchmarking results are to be taken into account in the analysis.
* The results must be discussed in an interdisciplinary manner and in cooperation with the Breast Cancer Centres.
 |  |  |
| 10.10 | Recording of follow-up dataA description is to be given of how follow-up data are collected and what the current follow-up status is (see outcome matrix). |  |  |
| 10.11 | The submission of the outcome quality matrix is only mandatory for Centres that have a functioning cancer registry. Clinical sites that apply for a reduction in the audit cycle or where – due to the positive assessment of the application – no on-site inspection takes place, are still obliged to submit the outcome quality matrix (follow-up rate ≥ 70%).  |  |

**Data Sheet**

An EXCEL template is available to Centres to record the indicators and data on outcome quality. This EXCEL template also contains an automatic evaluation of data quality. Only those presentations of indicators are eligible for certification which are undertaken on the basis of the EXCEL template provided by OnkoZert. The EXCEL template may not be changed.

The EXCEL template can be downloaded from [www.krebsgesellschaft.de](http://www.krebsgesellschaft.de/) and [www.onkozert.de](http://www.onkozert.de/)