**Catalogue of Requirements for**

**Centre for Haematological Neoplasia**

**of the German Cancer Society**

**Developed by the Certification Commission for Haematological Neoplasia Centres**

**Chairpersons of the Certification Commission:** Prof Dr F. Weißinger, Prof Dr S. Krause

**Members (in alphabetical order):**

ABO - Working Group Imaging in Oncology

ADT - Association of German Tumour Centres

AET - Hereditary Tumour Diseases Working Group

AGORS - Working Group for Rehabilitation and Social Medicine

AGSMO - Working Group on Supportive Measures in Oncology (

AIO - Working Group for Internal Oncology

AOP - Oncological Pathology Working Group

APM - Palliative Medicine Working Group

APO - Paediatric Oncology Working Group

ARO - Radiological Oncology Working Group

ASO - Working Group for Social Work in Oncology

BDI - Federal Association of German Internists

BDP - Federal Association of German Pathologists

BNHO - Professional Association of Registered Haematologists and Oncologists

BVDST Professional Association of German Radiotherapists

DEGRO - German Society for Radiooncology

DGfI - German Society for Immunology

DGHO - German Society for Haematology and Medical Oncology

DGIM - German Society for Internal Medicine

DGKL - German United Society for Clinical Chemistry and Laboratory Medicine

DGN - German Society for Nuclear Medicine

DGP - German Society for Palliative Medicine

DGP - German Society for Pathology

DGTI - German Society for Transfusion Medicine and Immunohaematology

DLH - German Leukaemia and Lymphoma Aid

DRG - German Radiological Society

DVSG - German Association for Social Work in Health Care

GfH - German Society for Human Genetics

GPOH - Society for Paediatric Oncology and Haematology

KOK - Conference on oncological nursing and paediatric nursing

OPH - Working Group for Oncological Pharmacy

PRIO - Working Group on Prevention and Integrative Medicine in Oncology

PSO - Working group for psycho-oncology

Representative of the S3 guideline Chronic lymphocytic leukaemia

Representative of the S3 guideline Follicular lymphoma

Representative of the S3 guideline Hodgkin's lymphoma

Representative of the S3 guideline on multiple myeloma

**Valid from 02.10.2023**

The changes marked "green" in this Catalogue of Requirements were adopted in 2022 and are valid for all audits carried out from 1 January 2023.

The Catalogue of Requirements for the 2023 audit year can continue to be used in the 2024 audit year, provided that any annual figures it contains are adjusted by the centre.

The Catalogue of Requirements form is based on the TNM classification of malignant tumours, 8th edition 2017 as well as the ICD classification ICD-10-GM 2023 (DIMDI) and the OPS classification OPS 2023 (DIMDI).

**Information on the** **Centre for Haematological Neoplasia**

|  |  |
| --- | --- |
| Centre name |  |
| Director of the Centre |  |
| Coordinator of the Centre |  |

|  |  |
| --- | --- |
| Clinical site (clinic/place) |  |
|  |  |

**QM system certification**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| QM system certification |  | Yes |  | no |

**Network/ Main co-operation partners**

The (main) cooperation partners of Centre for Haematological Neoplasia are registered with the certification institut OnkoZert in a "master data sheet" (*"Stammblatt"*). All the information contained therein is published on [**www.oncomap.de**](http://www.oncomap.de). The Centre must report all new and also all invalid cooperations. All other updates (changes in management, contact data etc.) must be corrected in the “master data sheet and must be regularly updated prior to the annual surveillance audit. This master data sheet can be requested from OnkoZert.

**Creation/ updating**

The electronically created questionnaire serves as the basis for the certification of the centre. The information provided here has been checked for correctness and completeness.

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| --- | --- |
| The data on outcome quality relate to the calendar year: |  |

|  |  |
| --- | --- |
| Date on which the questionnaire was compiled /updated |  |

**Table of contents**

1 General information about the centre

 1.1 Structure of the network

1.2 Interdisciplinary cooperation

1.3 Cooperation with referring physicians and aftercare treatment

1.4 Psycho-oncology

* 1. Social work and rehabilitation
	2. Patient participation
	3. Study management
	4. Nursing Care
	5. General service areas (pharmacy, nutrition counselling, speech therapy, …)
1. Organ-specific diagnostics
	1. Consultation hour
	2. Diagnostics
2. Radiology
3. Nuclear medicine
4. Surgical oncology

5.1 General surgical oncology

* 1. Organ-specific surgical oncology
1. Medicinal/internal oncology
	1. Haematology and oncology
	2. Organ-specific oncological systemic therapy
2. Radio - oncology
3. Pathology
4. Palliative care and hospice care
5. Tumour documentation/outcome quality

Annexes to the questionnaire (separate Excel document)

Data sheet (Excel template)

**1. General details of the Cancer Centre**

| **1.1 Structure of the network** |
| --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 1.1.1 | The following functions must be specified by name:* Director of the Centre
* Centre coordination

 Centre coordination - Tasks* Coordination of internal/ external audits
* Monitoring of Technical and Medical Requirements and ensuring compliance with them
* Communication interface
* Steering/monitoring of cross-specialty activities
 |  |
| 1.1.2 | Co-operation agreements Co-operation agreementsA cooperation agreement must be concluded with the external treatment partners involved in the cooperation. These must demonstrably fulfil the applicable professional requirements of this Catalogue of Requirements (not every service provider must also be a cooperation partner). The co-operation partners must be listed in the "Master Data Sheet" (administration via OnkoZert).If the cooperation partners of a centre work under one sponsorship or at one clinic location, written agreements are not necessary (implementation of the following points must nevertheless be ensured). The following points are to be regulated:* Competences and responsibilities.
* Description of the treatment processes relevant to the centre, taking into account the interfaces.
* Obligation to implement indicated Guidelines
* Description of the cooperation with regard to tumour documentation.
* Declaration of willingness to co-operate with regard to internal/external audits.
* Declaration of commitment to comply with the relevant DKG criteria and the annual provision of the relevant data.
 |  |
| 1.1.3 | Main co-operation partnerHaematology and oncology, radiation oncology, radiology, pathology Co-operation partner Pharmacy, palliative medicine, physiotherapy, psycho-oncology, self-help, social services, nuclear medicine, haematological diagnostics (in accordance with section 2.2), stem cell transplantation (in accordance with section 6.1.6 - no distance for cooperation partners), dermatology, neurology, spinal surgery (orthopaedics or neurosurgery), nephrology, surgery, microbiology, transfusion medicine |  |
| 1.1.4 | If stem cell transplants are carried out at the centre (see section 6.1.6), there are also cooperation agreements for consultation services and, if necessary, diagnostics and therapy with the following areas:* Gastroenterology (including endoscopy),
* Cardiology,
* Oral and maxillofacial surgery
* Neurosurgery,
* Ophthalmology,
* Ear, nose and throat medicine,
* Pulmonology (including bronchoscopy),
* Urology
* Dentistry
 |  |
| 1.1.5 | Cooperation with other certified organ cancer centres/ modules* For the treatment of lymphomas, cooperation agreements may exist with other certified organ cancer centres or modules (e.g. skin cancer centres or neuro-oncology centres).
* A cooperation agreement or SOP must define which treatment stages are provided by which cooperation partner.
* Counting of primary cases and patients with lymphoma is possible for both partners under these conditions.
* The cooperating centres must be named.
 |  |
| 1.1.6 | Presentation of the Centre for Haematological NeoplasiaThe structure of the centre must be presented as a whole and made public (e.g. Internet). This also includes the naming of all internal/ external co-operation partners with the following information:* Name, address of the co-operation partner
* Contact person with telephone number/ e-mail contact
 |  |
| 1.1.7 | Strategic planning/ reportingIt is recommended that an annual review be carried out at management level, in which the following aspects, for example, are considered:* Target definition/assessment, realignment of targets if necessary
* Consideration of audit results (internal/ external)
* Human resources for centre management (centre coordination)
* Public relations/ patient information
* Tumour documentation/ quality of results
 |  |

| **1.2 Interdisciplinary cooperation** |
| --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 1.2.1 | Number of patient casesThe centre must treat 75 patients per year with a diagnosis of haematological neoplasia.See ICD-10 list in the data sheet. Definition Pat. case:* Patients and not stays
* Patients after the age of 18
* Histological or cytological findings must be available
* Patients with initial diagnosis and all patients with recurrence or progression who are presented at the centre or the tumour board for the first time and receive essential parts of the therapy (systemic therapy, stem cell transplantation, active surveillance/watchful waiting) there
* The counting time is the time of the first presentation at the centre
* Patients may only be counted once for the centre regardless of the calendar year (even if another haematological neoplasia is diagnosed later) *Exception: double counting in cooperation with another certified organ cancer centre/module, see 1.1.5.*
* Patients who are only presented for a second opinion or only for consultation are not taken into account
* Complete recording in the tumour documentation system

 Definition of primary case (subset of patient cases):* Patients with primary disease
 |  |
| 1.2.2.a | Haematology and oncology case discussion * Department-internal, pre-therapeutic (or, in the case of emergency indications, earliest possible) discussion of all patients at the centre, if they are not already presented at the interdisciplinary tumour board (see Chapter 1.2.3).
* Participants: at least 2 haematology and oncology specialists.
* Content of the case discussion: e.g. diagnosis (taking into account haematological diagnostics), therapy planning, change of therapy, examination of the indication for stem cell transplantation, suitability for inclusion in clinical trials.
* If necessary, other disciplines should be consulted for the case discussion (e.g. haematological diagnostics (see chapter 2.2), pathology/ reference pathology, stem cell transplantation, radiation oncology, nuclear medicine, etc.).
* Patient-related documentation of the outcome of the case discussion.
 |  |
| 1.2.2.b | Transplant Meeting * If allogeneic stem cell transplantation is performed at the patient's own site, no separately recognised transplantation conference is required, see data sheet figures 5 and 6:
* Participants: at least 2 haematology and oncology specialists from the site, plus at least 1 haematology and oncology specialist from the transplanting institution
* Content of the tanslational meetings: prompt (3 weeks after initial/ relapse diagnosis) discussion of the indication for allogeneic stem cell transplantation in patients with acute leukaemia < 70 years of age
 |  |
| 1.2.3.a | Interdisciplinary tumour board CycleA tumour board must be held at least once a week. Participants (at specialist level):Haematology and oncology, radiology, radiooncology, pathology Participation depending on the issue: e.g. surgical disciplines, nuclear medicine, nephrology, palliative medicine, oncological care Patient presentation:* All patients with ~~malignant lymphoma,~~ Hodgkin's lymphoma, non-Hodgkin's lymphoma, Burkitt's ALL, Burkitt's lymphoma or plasma cell neoplasia must be presented pre-therapeutically (exception: emergency therapy initiation).
* Recurrent/ refractory patients with ~~malignant lymphoma,~~ Hodgkin's lymphoma, non-Hodgkin's lymphoma, Burkitt's ALL, Burkitt's lymphoma or plasma cell neoplasia as well as other complex cases with haematological neoplasia should be presented as required.

 Extent of primary cases discussed with ~~malignant lymphoma,~~ Hodgkin's lymphoma, non-Hodgkin's lymphoma, Burkitt's ALL, Burkitt's lymphoma or plasma cell neoplasia: ≥95% |  |
| 1.2.3.b | General requirements for tumour boards Several co-operation partnersIf several cooperation partners are named for a specialisation, the presence of a representative is sufficient if a regulated exchange of information has been established between them (e.g. via quality circles).Each cooperation partner must participate in at least 30% of the tumour boards. |  |
| 1.2.3.c | Web/ online tumour boardIf web tumour board are used, it must be possible to transmit the sound and documents presented. It must be possible for each main cooperation partner to present its own documents/ imaging material. Telephone tumour board with no imaging material are not an option. |  |
| 1.2.3.d | Tumour board process descriptionThe process of registration, preparation, implementation and recording of the tumour board must be described in a procedural instruction. |  |
| 1.2.3.e | Demonstration imaging materialPatient-related image material (e.g. pathology, radiology) must be available at the tumour board and suitable technical equipment must be available for displaying the image material. Computerised presentation is sufficient. |  |
| 1.2.3.f | Preparation for tumour boardThe main patient and treatment data are to be compiled in writing beforehand and made available to the participants at the tumour board. A pre-appraisal of suitable study patients is to be undertaken. |  |
| 1.2.3.g | Minutes of the tumour board* The results of the tumour board include a written, interdisciplinary treatment plan ("tumour board protocol").
* The minutes of the tumour board must be part of the patient file and
* The recommendation of the tumour board should also form part of the doctor's letter.
* The "Tumour board minutes" should be generated automatically from the tumour documentation system.

 Result of tumour boardThe patient must be informed about the recommendations of the tumour board. |  |
| 1.2.3.h | Participation tumour board as continuing educationFor the following functions/ professional groups, a one-time mandatory participation in the tumour board is to be made possible (refresher every 3 years):* Assistants (MTA, TRA, ...) from the fields of radiology, nuclear medicine and radiooncology
* ~~Nursing,~~ social services, psycho-oncology and pharmacy staff
* ~~Oncological specialist nurse and at least 2 nursing staff per treatment unit~~

Participation in the tumour board is recognised as continuing education for the afore-mentioned functions/ professional groups. |  |
| 1.2.4 | Treatment plan* An individualised interdisciplinary treatment plan must be drawn up for all patients. This also applies to patients who are not presented to a tumour board.
* A standardised documentation template for the treatment plan and tumour board protocol is recommended.
 |  |
| 1.2.5 | Therapy deviation* In principle, treatment plans and recommendations from the tumour board are binding.
* If deviations from the original treatment plan or deviations from the guidelines are identified, these must be recorded and evaluated. Depending on the cause, measures must be taken to avoid deviations.
* If a therapy is not started at the patient's request (despite an existing indication) or is cancelled prematurely, this must also be recorded.
 |  |
| 1.2.6 | ~~Guidelines~~ Care according to the current state of medical knowledge* The current information from the S3 guidelines and Onkopedia guidelines should be translated into SOPs (definition of the standard for diagnostics, therapy and aftercare, specifying responsibilities). In addition to general diagnostic and therapeutic algorithms, more complex, recurring or cross-entity situations (e.g. emergency radiotherapy) should be addressed in particular.
* For haematological neoplasms for which no guidelines exist, SOPs must be defined in internal processes (e.g. as part of a quality circle).
* For rare entities, a general care plan must be provided that defines the basic processes for determining diagnostics and therapy.
* The standards and SOPs must be updated and publicised by the person responsible for the guidelines (see section 1.2.7). Implementation must be checked by means of suitable measures. The process must be described.
* For patients with myelon compression and neurological symptoms, an SOP for treatment must be drawn up within 24 hours of the suspected diagnosis.
 |  |
| 1.2.7 | Tasks of the person responsible for the guidelines* Monitoring of up-to-dateness and further development.
* Announcement of the contents of the guidelines to new employees (description of the type of announcement and recording).
* Monitoring of guideline implementation (e.g. guideline audit, data monitoring).

 In the event of a change in guidelines* Systematic, prompt and verifiable notification of changes (recorded e.g. in the form of training courses, Q-circles).
* Changes to internal processes/ guidelines due to the amended guidelines.
 |  |
| 1.2.8 | Quality circle* The tasks, participants and content of the quality circles must be defined.
* Quality circles must be organised at least three times a year.
* A list of participants is kept.
* Morbidity/mortality conferences are also recognised as quality circles.
* The quality circles must produce clear results (actions, decisions) that appear suitable for a significant further development/improvement of the Haematological Neoplasia Centre.
* The outcome of the quality circle must be recorded.

 Possible topics:* Analysing the quality of results (benchmarking)
* Interdisciplinary continuing education
* Interdisciplinary case reviews
* Structural improvements to the centre
* Public relations

 A quality circle must have taken place at the time of initial certification. The result of the quality circle must be recorded. |  |
| 1.2.9 | Morbidity/ mortality conferences (M&M conference)* Invited participants are the participants of the tumour board and the referring physicians
* Conference can be scheduled to coincide with the tumour board or with events for referring physicians
* Both negative and positive cases must be presented. M&M conferences must be held twice a year.
* M&M conferences must be recorded.
 |  |

| **1.3 Cooperation referrers and aftercare** |
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| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 1.3.1 | Cooperating referrersAn up-to-date list is to be kept of the cooperating referrers. The referrers are to be informed about cooperation within the Centre with regard to the following details: Duties of the centre:* Referrers are entitled to attend the tumour board when their patients are presented.
* Referrers are to be given the opportunity to present patients in the tumour board.
 |  |
| 1.3.2 | ContactsThe Centre's contacts are to be given to the re-ferrers in line with their function (e.g. telephone number, email). This can be done with the re-quired publication of the cooperation partners. |  |
| 1.3.3 | Provision of documentsThe following documents must be provided promptly to the person making the referral:* Histology
* Tumour board protocol/ treatment plan
* Surgical report (optional)
* Doctor's letter/ discharge letter
* Changes to therapy
 |  |
| 1.3.4 | Feedback systemA written procedure must be set up for the recording, processing and feedback of general and case-related concerns/ questions/ complications from referring physicians. |  |
| 1.3.5 | Referrer satisfaction Catalogue of Requirements* Every three years a referrer satisfaction survey must be conducted. The results of this survey are to be evaluated and analysed. A cross-department survey can be recognised.
* The referrer satisfaction survey must be available for the first time for the first surveillance audit (1 year after initial certification).
 |  |
| 1.3.6 | Continuing educationEvents for the exchange of experience and continuing education events are to be proposed at least twice a year by the Centre. Contents/ results and participation are to be recorded. |  |

| **1.4 Psycho-oncology** |
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| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 1.4.1 | Psycho-oncology qualification* Diploma/ Master's degree in psychology that qualifies for a scientifically recognised psychotherapy method,
* Physicians,
* Diploma/ Master's degree in social pedagogy, qualified for a scientifically recognised psychotherapy method,

 with at least 1 psychotherapeutic specialty training : behavioural therapy, psychodynamic psychotherapy (analytical psychotherapy and depth psychology-based psychotherapy), 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 addiction disorders and for the psychotherapeutic co-treatment of somatic diseases and psycho-oncological training (DKG-recognised) Grandfathering for all those who are currently recognised and those who have started DKG-recognised psycho-oncological training by 31 December 2019. Licence to practise: At least 1 person in the psycho-oncological team of the network (inpatient or outpatient) must be licensed (psychological or medical psychotherapist). Representatives of other psychosocial professions may be authorised if they can provide proof of the above-mentioned additional qualifications. A case-by-case assessment is required for this. |  |
| 1.4.2 | Offer and accessEach patient must be offered the option of psycho-oncological counselling in a timely manner in the vicinity. The offer must be made in a low-threshold manner. Documentation and evaluationTo identify treatment needs it is necessary to conduct standardised screening for mental strain (see Indicator "Psycho-oncological distress screening"), and to document the result. The proportion of patients with excessive stress in the distress screening should be presented. Psycho-oncological counsellingPsycho-oncological care, in particular for patients with excessive stress in the distress screening, must be presented. |  |
| 1.4.3 | Psycho-oncology resourcesAt least 1 psycho-oncologist with the above-mentioned qualifications is available to the centre (by name). |  |
| 1.4.4 | Scope of supply* The number of patients who have received psycho-oncological care must be recorded.
* The frequency and duration of the conversations must be recorded.
 |  |
| 1.4.5 | PremisesA suitable room must be provided for psycho-oncological patient consultations. |  |
| 1.4.6 | Organisation planThe performance of tasks is to be regulated by an organisational plan in which, among other things, the availability of resources and the local presence can be seen. |  |
| 1.4.7.a | Psycho-oncology - task profilePsycho-oncological care for patients must be offered in all phases of care (diagnosis, inpatient, post-inpatient). |  |
| 1.4.7.b | Goals and tasks of care:* Diagnostic clarification after positive screening
* Prevention/ treatment of secondary psychosocial problems
* Activation of personal coping resources
* Maintaining the quality of life
* Consideration of the social environment
* Organisation of further outpatient care through cooperation with outpatient psycho-oncological service providers
* Public relations work (patient event, etc.)
* Management of the psychosocial quality circle
 |  |
| 1.4.7.c | Recommended:* To offer and coordinate the implementation of supervision, further education and training programmes for employees.
* A twice-yearly meeting between psycho-oncologists and the nursing and medical staff.
* Regular written and, if necessary, verbal feedback on psycho-oncological activities to the medical practitioners (e.g. consultation report or documentation in the medical file).
* Regular participation in ward conferences and tumour boards.
* Cooperation with social services and other centres.
* Offer or coordinate interdisciplinary intervention programmes.
* The psycho-oncologists should present their work at least twice a year at the tumour board.
 |  |
| 1.4.8 | Documentation and evaluationTo identify the need for treatment, it is necessary to carry out a screening for psychological stress (see S3 guideline on psycho-oncology).Psycho-oncological care must be documented and evaluated on an ongoing basis using suitable instruments. |  |
| 1.4.9 | Training/ further training/ supervision* At least 1 specific training programme per employee per year (at least 1 day per year).
* External supervision must be provided on a regular basis (recommendation: twice a month).
 |  |

| **1.5 Social work and rehabilitation** |
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| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 1.5.1 | Social work - qualification* Social worker/ social pedagogue
* Individual case reviews in accordance with the guidelines of the professional association are possible
* Additional qualification
* Experience in medical/ oncological professional field
 |  |
| 1.5.2 | Offer and accessEvery patient must be offered the possibility of counselling by the social service in all phases of the disease, locally and promptly (proof required). The offer must be made without any barriers. |  |
| 1.5.3 | ResourcesAt least 1 staff member is available to advise patients in the centre for 400 patients (not cases) advised in the centre (= primary cases, secondary metastases, recurrences). The personnel resources can be provided centrally; an organisational plan must be available. |  |
| 1.5.4 | Scope of patient careThe number of patients who have received care from social services must be documented and analysed. |  |
| 1.5.5 | PremisesA suitable room must be provided for social counselling work. |  |
| 1.5.6 | Organisation planThe performance of tasks is to be regulated by an organisational plan in which, among other things, the availability of resources and the local presence can be seen. |  |
| 1.5.7 | Contents of the counselling:using the DVSG service catalogue and the expert standard PEOPSA (initial psychosocial counselling of oncological patients by social work):* Identification of social, economic and psychological emergencies.
* Initiation of medical rehabilitation measures.
* Advice on social law and economic issues (e.g. law on severely disabled persons, wage replacement, pensions, benefit requirements, personal contributions, etc.).
* Support with application procedures.
* Advice on outpatient and inpatient care options and referral to support services and specialist services.
* Support with professional and social reintegration.
* Co-operation with service providers and service providers.
* Discharge management.
* Intervention in emergencies.
 |  |
| 1.5.8 | Further tasks:* Offer further training/ information events for other disciplines at the centre and/ or patients.
* Public relations and networking
* Participation in multi-professional case discussions, supervision.
* Interdisciplinary co-operation, in particular with doctors, nurses, physiotherapists, psycho-oncologists, pastoral care, etc.
 |  |
| 1.5.9 | Documentation and evaluationThe activities of the social workers must be documented (e.g. CareSD, HIS) and evaluated. |  |
| 1.5.10 | Further education* At least 1 specific training programme per employee per year (at least 1 day per year).
* Offer of supervision
 |  |
| 1.5.11 | Patient-related selection of rehabilitation facilitiesIf indicated, patients should be offered oncological rehabilitation during the consultation (see also Chapter 1.5.7). |  |

| **1.6 Patient involvement** |
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| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 1.6.1 | Patient interviews:* At least every 3 years, all patients should be given the opportunity to take part in the patient survey for at least 3 months.
* Survey possible as part of a survey of the entire hospital (prerequisite: targeted analysis of the centre's patients is possible)
* The response rate should be over 30% (initiate measures if this is not achieved).
 |  |
| 1.6.2 | Evaluation of patient survey* The responsibility for the evaluation must be defined.
* The evaluation must refer to the patients of the Centre for Haematological Neoplasia.
* A recorded evaluation must be made and presented during the audit.
* Actions are to be defined on the basis of the evaluation.
 |  |
| 1.6.3 | Patient information (general)* The centre must present itself and its treatment options in a comprehensive manner (e.g. in a brochure, patient folder, on the homepage).
* The co-operation partners and their contact persons must be named. The treatment programme must be described.
* The treatment programme presented must include Rehab/ AHB, self-help, treatment measures and alternatives.
 |  |
| 1.6.4 | Discharge interviewA discussion is held with each patient on discharge (brief documentation/ checklist) in which at least the following topics are addressed and relevant information is provided:* Therapy planning
* Individualised aftercare plan (handover of aftercare pass)
 |  |
| 1.6.5 | Event for Pat.The Centre for Haematological Neoplasia must hold an information event for patients and/or interested parties at least once a year. If possible in co-operation with self-help groups.If patient events are (co-)financed by industry, this fact including potential conflicts of interest of the speakers must be disclosed. The centre must rule out any direct influence on patients by industry representatives. |  |
| 1.6.6 | Complaints managementA regulated complaints management system is in place. Patients receive feedback. Complaints are taken into account in the improvement process. |  |
| 1.6.7 | Self-help groupsThe self-help groups with which the Centre for Haematological Neoplasia actively cooperates must be named.* A contact person must be named.
* The tasks of the self-help groups can only be carried out by members of the self-help groups.
 |  |
| 1.6.8 | Written agreements should be made with the self-help groups. These should be updated at least every 5 years and include the following points:* Access to self-help groups in all phases of care (initial diagnosis, hospitalisation, chemotherapy, aftercare, etc.).
* Announcement of contact details of self-help groups (e.g. in patient brochures, homepage of the centre).
* Possibilities Display of information brochures from self-help groups.
* Regular provision of rooms at the centre for patient consultations.
* Quality circles involving representatives from psycho-oncology, self-help groups, social services, pastoral care, nursing and medicine.
* Personal discussions between self-help groups and the Centre for Haematological Neoplasia with the aim of organising joint activities and events or coordinating them with each other. The result of the discussion must be recorded.
* Participation of medical staff in events organised by the self-help group.
 |  |

| **1.7 Study management** |
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| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 1.7.1 | Access to studiesPatients must have access to studies. The studies conducted at the Centre for Haematological Neoplasia must be listed and published, e.g. on the homepage. |  |
| 1.7.2 | Study representativeThe doctor in charge of studies must be named. Study assistance* One study assistant per "conducting study unit" must be named in the "study organisation chart".
* This can be active for several "performing study units" in parallel.
 |  |
| 1.7.3 | Study Assistance - Qualification Vocational trainingSpecialised medical training (e.g. MTA, healthcare/ nursing assistant, medical assistant) EducationSpecific training for the study assistant function must be demonstrated (guideline: course lasting several days).At least one course application must be submitted at the time of initial certification. The course must be completed within one year. During the training programme, the investigator/ study representative must compensate for any qualification deficits. |  |
| 1.7.4 | Study assistance - TasksThe range of tasks must be defined in writing (e.g. via job/ function description) and may include the following contents, among others:* Conducting studies together with the doctor in charge of the study
* Patient care during the study and in aftercare
* Organisation, coordination of diagnostics, laboratory, sample dispatch and test medication
* Collection and documentation of all study-relevant data
* Preparation and monitoring of audits and inspections by authorities
* The work of a study assistant can be combined with other activities such as tumour documentation.
 |  |
| 1.7.5 | Proportion study patients 1.initial certification:At the time of initial certification, ≥1 patient must have been enrolled in studies.2.after 1 year:At least 5% of the primary case number. Only the inclusion of patients in studies with an ethics vote counts as study participation (non-interventional/ diagnostic studies and prevention studies are also recognised; biobank collections alone are excluded). All study patients can be taken into account for the calculation of the study quota (proportion of study patients in relation to the primary case number of the centre).General requirements for the definition of study quota:* Patients can be counted once per study, time: date of patient consent.
* Patients in the palliative and adjuvant situation can be counted, no restriction of stages.
* Patients who are enrolled in several studies at the same time can be counted more than once.
 |  |
| 1.7.6 | Process description:For the initiation of new studies and the conduct of studies, the processes including responsibilities must be defined for each "conducting unit", unless centrally regulated. This includes, for example:* Selection of new studies incl. approval decision
* Internal announcement of new studies (update of study list,...)
* Study organisation (special features of supervision, documentation,...)
* Type of disclosure of study results (e.g. employees, patients)
 |  |
| 1.7.7 | Cooperation between study groups* The centre participates in studies conducted by supra-regional academic study groups (e.g. the groups in the Leukaemia Competence Network and the German Lymphoma Alliance).
* If patients with acute leukaemia are treated at the centre, cooperation with the GM-ALL and an AML study group is strongly recommended.
 |  |

| **1.8 Nursing care** |
| --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 1.8.1 | Oncological specialist nurses* At least 1 active oncology nurse must be involved in the Centre for Haematological Neoplasia.
* Oncological nurses are to be designated by name.
* In areas where patients are cared for, evidence must be provided that an oncological specialist nurse is working in each case.
* In inpatient areas where patients are cared for, the activity of an oncology nurse must be verified. The performance of duties/ representation must be regulated and documented in writing.

  The precondition for recognition as a specialist oncology nurse is* specialty training specialist oncology nurse in line with the respective federal state regulations
* with the Model Federal State Ordinance of the German Hospital Federation (Deutsche Krankenhausgesellschaft e.V.)·
* or advanced practice nurse (master title) plus 2 years’ practical professional experience (equivalent to a full-time position) in the oncological field to be certified.
 |  |
| 1.8.2 | Responsibilities/tasks Patient-related tasks:* Specialist assessment of symptoms, side effects and stress.
* Individualised derivation of interventions from nursing standards.
* Implementation and evaluation of nursing and therapeutic measures.
* Determination of individual patient-related counselling needs.
* The need for specialist advice must already be defined as part of the care concept of the individual organ centres.
* Continuous information and counselling of the patient (and their relatives) during the entire course of the illness.
* Implementation, coordination and verification of structured counselling sessions and guidance for patients and relatives; according to the concept, these can also be carried out by other experienced nursing staff with oncological expertise.
* Participation in the tumour board (according to chapter 1.2).
* Initiation of and participation in multi-professional case discussions/ nursing rounds; the aim is to find solutions in complex care situations; criteria for the selection of patients must be defined; at least 12 case discussions/ nursing rounds must be demonstrated per year and centre.

 Superordinate activities:* A nursing concept must be developed and implemented in which the organ-specific features of oncological care in the organ cancer centres/ modules are taken into account.
* Drawing up of specialised, in-house standards on the basis of (if possible) evidence-based guidelines (e.g. S3-LL Supportive).
* Offer of collegial counselling/ supervision.
* Networking of oncology nurses in a joint quality circle and participation in the quality circle of the Centre for Haematological Neoplasia.
* Interdisciplinary exchange with all professional groups involved in treatment
* Responsibility for implementing the requirements for the nurse administering chemotherapy (see chapter 6.2.3).
 |  |
| 1.8.3 | FamiliarisationThe induction of new employees must be carried out on the basis of an oncological induction catalogue/ plan with the involvement of the oncological specialist. |  |
| 1.8.5 | Continuing education* A qualification plan for the nursing staff must be submitted in which the qualifications planned for a one-year period are presented.
* At least 1 specific training/ further training per employee per year (at least 1 day per year), provided that the employee performs quality-relevant activities for the Centre for Haematological Neoplasia.
 |  |

| **1.9 General service areas (pharmacy, nutritional counselling, speech therapy...)** |
| --- |
| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 1.9.1 | Availability of blood products:* Supply of blood products to patients in an emergency is guaranteed (24/7)
* Supply of irradiated blood products is guaranteed 24/7
* Supply of targeted (HLA-matched) platelets is ensured
 |  |
| 1.9.2 | Pharmacy* The preparation of cytostatic solutions and the availability of urgently required medicines must also be guaranteed for emergencies at weekends and on public holidays.
* This can be ensured by the pharmacy being on call or a medication plan for medical staff (description of the preparation/ availability of the required medication and standardised workstations).
 |  |

**2. Organ-specific diagnostics**

| **2.1 Consulting hours** |
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| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 2.1.1 | Information/ dialogue with patientsWith regard to diagnosis and treatment planning, sufficient information must be provided and an adequate dialogue must be conducted. This includes, among other things:* Presentation of alternative treatment concepts.
* Offer and mediation of second opinions.
* Final meetings as standard.

 The manner in which information is provided and the dialogue is to be described in general terms. This must be documented in the patient's medical notes and protocols/ records. |  |
| 2.1.2 | Organisation of the consultationFor the realisation of the consultation hour is a* Specialist in internal medicine and haematology and oncology responsible.
 |  |
| 2.1.3 | The consultation must cover the following topics:* Initial examination after suspected diagnosis or confirmation of diagnosis.
* Planning of the further diagnostic procedure.
* Referral to the interdisciplinary tumour board.
* Planning of the further therapeutic procedure (in accordance with the decision of the tumour board).
* Care of patients undergoing maintenance therapy.
* Follow-up care (especially with regard to recurrence diagnostics, secondary neoplasia and organ toxicity).
* Information on the significance of complementary and alternative medical procedures in accordance with S3 guidelines (e.g. immunomodulatory effects of mistletoe therapy).
* Toxicity management and supportive therapy.
 |  |
| 2.1.4 | Fertility preservation* All patients with haematological neoplasia and planned fertility-reducing therapy should be offered pre-therapeutic information on fertility-preserving measures.
* The content of the consultation must be specifically focussed on the entity to be treated and the planned therapies (in accordance with the S2k guideline on fertility preservation).
* A procedural instruction with the names of those responsible must be provided.
* An andrology unit and a gynaecology unit with experience in this field are either available at the facility or a connection is ensured for additional counselling and/ or the implementation of fertility-preserving measures.
 |  |
| 2.1.5 | Waiting times during consultation hoursRequirement: <60 min. (target value) Waiting times for an appointmentRequirement: <2 weeks Waiting times should be recorded on a random basis and statistically analysed (recommendation: evaluation period of 4 weeks per year). |  |
| 2.1.6 | The following services/ methods must be provided during consultation hours:* Access to imaging
* Access to laboratory diagnostics including haematological diagnostics (see chapter 2.2)
* Bone marrow punctures
* Sonography, including lymph node sonography
* Lumbar puncture
 |  |
| 2.1.7 | The following quality-determining processes are to be described with details of responsibilities:* Preparation of patients for the tumour board.
* Inpatient admission.

Sufficient resources must be available for the execution of the processes. |  |
| 2.1.8 | If children with haematological neoplasms are also treated at the site, an orderly transition to the adult sector should be implemented for patients over the age of 18 in interdisciplinary collaboration with paediatrics. The processes and standards must be described. |  |

| **2.2 Diagnostics** |
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| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 2.2.1.a | Haematological diagnostics:Cytomorphology and flow cytometryThe following procedures are available to patients at the centre:* Cytomorphology
	+ Light microscopic examination of smears of peripheral blood, bone marrow and other suitable liquid puncture materials (e.g. cerebrospinal fluid, ascites, pleural fluid)
	+ Availability of cytomorphology in the centre
	+ Results must be available on the day of collection. The underlying processes must be described.
* Flow cytometry (external cooperation possible, no distance limit, cooperation can also be described via SOP instead of a cooperation agreement): Notification of results must be possible by the following working day.

 Naming of the unit performing the diagnostics  |  |
| 2.2.1.b | Availability CytomorphologyCytomorphological diagnostics must also be guaranteed for emergencies at weekends and on public holidays. |  |
| 2.2.1.c | Qualification of findings* Diagnosis by a specialist in internal medicine and haematology and oncology or a specialist in pathology or a specialist in laboratory medicine with special experience in haematological diagnostics.
* Substitution regulations with the same qualification must be documented in writing.
* Specialist and representative must be named.
 |  |
| 2.2.1.d | Quality assurance diagnostic unit* The unit has an internal quality management system.
* Flow cytometry additionally: daily device-specific internal quality control and fluorescence calibration if necessary.
* The Institute regularly and successfully participates in quality assurance measures, in particular in round robin tests organised by reference institutions of the German Medical Association.
* In particular, successful participation in round robin tests on flow cytometry and cytomorphology should be demonstrated.
 |  |
| 2.2.2.a | Haematological diagnostics:Cytogenetics, molecular genetics, immunogeneticsThe following procedures are available to patients at the centre (external cooperation possible):·      Cytogeneticso Karyotypingo Fluorescence in situ hybridisation (FISH)·      Molecular geneticso Polymerase chain reaction (PCR)o Gene sequencing·      Immunogeneticso HLA typingo HLA antibodies Naming of the unit performing the diagnostics |  |
| 2.2.2.b | Quality assurance diagnostic unit* The unit has an internal quality management system. Certification/ accreditation (e.g. in accordance with DIN EN ISO 15189) should be sought.
* The guidelines of the German Medical Association for the quality assurance of laboratory medical examinations (available at Link), in particular section B5, are complied with.
* The unit regularly and successfully participates in quality assurance measures, in particular in round robin tests organised by reference institutions of the German Medical Association.
 |  |

**3. Radiology**

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| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 3.1 | Specialists* At least 1 radiology specialist
* Substitution regulation with the same qualification must be documented in writing
* Specialist and representative must be named
 |  |
| 3.2 | Medical-technical radiology assistants (MTR)At least 2 qualified MTRs must be available. |  |
| 3.3 | Methods to be used in radiology:* Conventional X-ray
* Sonography
* Spiral CT
* MRI (field strength at least 1.5 Tesla)
 |  |
| 3.4 | Radiology process descriptions (SOPs)The imaging procedures must be described and checked once a year to ensure that they are up to date. |  |
| 3.5 | Creation of findingsThe radiologist's written findings must be available to the co-treating physicians no later than 24 hours after the examination. |  |
| 3.6 | Induction training for new employeesA systematic, recorded induction for new employees must be ensured, which imparts knowledge of the centre in relation to the respective area of activity.This familiarisation must take place within 3 months of the start of employment. |  |
| 3.7 | Continuing education/ specialty training* A qualification plan for the medical and assistant staff must be submitted in which the qualifications planned for a one-year period are presented.
* At least 1 specific training/ further training per employee per year (at least 1 day per year), provided that the employee performs quality-relevant activities for the Centre for Haematological Neoplasia.
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**4. Nuclear medicine**

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| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 4.1 | Specialists in nuclear medicine* At least 1 specialist in nuclear medicine is available
* Substitution regulation with the same qualification must be documented in writing
* Specialist and representative must be named
 |  |
| 4.2 | MTR (= medical technologists for radiology) of nuclear medicineAt least 2 qualified MTRs must be available. |  |
| 4.3 | Methods to be used in nuclear medicine* Access to FDG-PET-CT or PET-MRI must be ensured.
 |  |
| 4.4 | Process descriptions (SOPs)The imaging procedures in nuclear medicine must be described and reviewed once a year to ensure that they are up to date. |  |
| 4.5 | Creation of findingsThe written findings of the nuclear medicine specialist must be available to the co-treating physicians no later than 24 hours after the examination. |  |
| 4.6 | Induction training for new employeesA systematic, recorded induction for new employees must be ensured, which imparts knowledge of the centre in relation to the respective area of activity.This familiarisation must take place within 3 months of the start of employment. |  |
| 4.7 | Continuing education* A qualification plan for the medical and nursing staff must be submitted in which the qualifications planned for a one-year period are presented.
* At least 1 specific further education/ training course per employee per year (at least 1 day per year), provided that the employee performs quality-relevant activities for the Centre for Haematological Neoplasia.
 |  |

**5. Surgical oncology**

| **5.1 Cross-organ surgical therapy** |
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| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 5.1 | The Catalogue of Requirements of the organ cancer centres and the oncology centre have a standardised table of contents.For haematological neoplasia centres, this chapter does not contain technical requirements. |  |

| **5.2 Organ-specific surgical therapy** |
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| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 5.2 | The Catalogue of Requirements of the organ cancer centres and the oncology centre have a standardised table of contents.For haematological neoplasia centres, this chapter does not contain technical requirements. |  |

**6. Medicinal oncology / Systemic therapy**

| **6.1 Medical oncology** |
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| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 6.1.1 | The Centre for Haematological Neoplasia has an independent bed-managing department for haematology and oncology. |  |
| 6.1.2 | Medical qualification Head of specialised department* Specialist in internal medicine and haematology and oncology.
* Authorisation for further training as a specialist in internal medicine and haematology and oncology from the relevant medical association.
* A representative with the above-mentioned qualifications must be appointed.
 |  |
| 6.1.3 | Availability Specialist in haematology and oncology in the department providing the bed* Presence of at least one specialist doctor on weekdays during regular working hours.
* 24-hour/ 7-day availability of a specialist doctor (on-call service).

At least 3 full-time positions. |  |
| 6.1.4 | Ward round at the weekend* Weekend ward round by a doctor from the haematology and oncology department.
 |  |
| 6.1.5 | * Isolation of patients and reverse isolation must be possible and appropriate measures (e.g. hand disinfection, screening for problem germs, filters) must be regulated (procedural instructions).
* Compliance with measures to reduce infections caused by airborne and waterborne germs for stem cell transplants (see also Chapter 6.1.6 g)) and for patients with acute leukaemia (reference in particular to the "Requirements for hygiene in the medical care of immunosuppressed people" of the Robert Koch Institute).
* Individual monitoring stations or monitors and access to intensive care must be available at all times in the same hospital for patients with haematological neoplasia.
 |  |
| 6.1.6.a | Stem cell transplantation and CAR T-cell therapy(no distance limit for co-operation partners)* The possibility of allogeneic and autologous stem cell transplantation and CAR-T cell therapy must be available.
* Allogeneic and/ or autologous stem cell transplants and/ or CAR T-cell therapies can also be provided by an external cooperation partner (written cooperation agreement required).
* The co-operation partner for stem cell transplantation and CAR T-cell therapy must be named.
* The co-operation agreement must define which treatment stages are provided by which cooperation partner. Counting patient cases is possible for both partners under these conditions.
* The external cooperation partner for stem cell transplantation must itself be part of a centre for haematological neoplasia. Alternatively, fulfilment of the requirements 6.1.6 b) to i) must be proven (proof also possible via JACIE accreditation, see chapter 6.1.6 c)).
* In particular, the cooperation agreement must contain regulations for the transfer of patients to the unit for stem cell transplantation and preparation of allogeneic transplants (e.g. HLA typing).
* For patients with acute leukaemia <70 years of age, HLA typing and presentation at the CMT conference at the start of induction chemotherapy must be ensured together with the cooperation partner for stem cell transplantation.
 |  |
| 6.1.6.b | The following stem cell transplantation procedures must be available (in co-operation if necessary):* Autologous stem cell transplantation
* Allogeneic stem cell transplantation

o HLA-compatible (family donation)o HLA-compatible (foreign donation)o Haploident |  |
| 6.1.6.c | The guidelines for the production and use of haematopoietic stem cell preparations issued by the German Medical Association must be complied with. In particular, the following requirements (6.1.6 d) to 6.1.6 i)) must be fulfilled.A valid accreditation according to the guidelines of the "Joint Accreditation Committee ISCT-Europe & EBMT" (JACIE) can replace the proof of the following requirements (6.1.6 d) to 6.1.6 j)). |  |
| 6.1.6.d | Management - Qualification:Head and deputy head of the unit for allogeneic and autologous stem cell transplantation* Specialist in internal medicine and haematology and oncology
* At least 2 years of professional experience in unit for allogeneic and autologous stem cell transplantation

 Head of the unit for allogeneic and autologous stem cell transplantation* Personal experience with at least 50 allogeneic stem cell transplants
 |  |
| 6.1.6.e | Nursing staff* Staffing for allogeneic stem cell transplants corresponding to at least one intermediate care unit.
 |  |
| 6.1.6.f | Additional staffRegular availability of the following areas:* Transplant coordination for preparation, planning and implementation
* Documentary for documentation and data reporting
* Physiotherapy
* Nutritional counselling
* Hygiene monitoring.
 |  |
| 6.1.6.g | Spatial conditions* Compliance with measures to reduce infections caused by airborne and waterborne germs (reference in particular to the "Hygiene requirements for the medical care of immunocompromised people" of the Robert Koch Institute).
* Outpatient care, aftercare or follow-up care in a separate area with the option of isolating patients.
* Provision of sufficient bed capacity for the readmission of patients with transplant-specific problems (proof e.g. based on the bed plan).
 |  |
| 6.1.6.h | Preparation and implementation of stem cell transplantsThere are procedural instructions specifying responsibilities for the following processes: * Coordination of donor selection, preliminary examination and treatment
* Patient information and consent
* Conditioning programmes and radiation concept
* Administration of the HSZZ
* Prophylactic or interventional donor lymphocyte administration
* Prophylaxis of common complications
* Recognition and treatment of common complications
* Aplasia management
* Hygiene regulations, infection prophylaxis and therapy
* Transfusion concept
 |  |
| 6.1.6.i | DocumentationMandatory reporting of transplant cases to the German Register for Stem Cell Transplantation. |  |
| 6.1.7 | Further education* A qualification plan for the medical and nursing staff must be submitted in which the qualifications planned for a one-year period are presented.
* At least 1 specific training/ further training per employee per year (at least 1 day per year), provided that the employee performs quality-relevant activities for the centre.
 |  |

| **6.2 Organ-specific systemic therapy** |
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| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 6.2.1 | The following statements refer to the following co-operation partners: General noteThe requirements in this section of the questionnaire must be verified individually by each cooperation partner of the centre for the area of medical oncological therapy. Therefore, this section must be completed specifically by each cooperation partner in this speciality or specific statements must be made by each cooperation partner in this section.This also applies if inpatient and outpatient therapy is provided by different co-operation partners (separation of inpatient/ outpatient). |  |
| 6.2.2 | Implementation of drug-based tumour therapy (e.g. chemotherapy, AK therapy, cellular therapy) Specialist for* Internal medicine and haematology and oncology

 A representative with the above qualifications must be appointed.The specialists named here must supervise the oncological drug therapy. It is not possible to delegate responsibilities to doctors without the above qualifications. |  |
| 6.2.3 | Carer/ MFA (outpatient/ inpatient)Requirements for the carer who administers chemotherapy:* Inpatient, day-care or outpatient areas in which oncological drug therapy is carried out by non-medical staff must be under the supervision of an oncological nurse. Co-operating practices are not affected by this regulation.
* At least 1 year of professional experience in oncology.
* Proof of 50 chemotherapy applications/ year must be provided (an estimate is possible for initial certification; in subsequent years, proof must be provided in the audit).
* Proof of training in accordance with the recommendations of the KOK (KOK recommendation for action, application of cytostatics by nursing staff).
* Active involvement in the implementation of the requirements for emergency treatment and therapy of concomitant and secondary diseases. Nursing counselling and/ or education of patients must be documented.
* Proof of qualification for the application of chemotherapeutic agents by the medical specialists named under 6.2.2. Proof of annual training, including the content of 6.2.10 and 6.2.11, is required for the qualification.
 |  |
| 6.2.4 | Case numbers per treatment unit* At least 200 drug-based tumour therapies (cytostatic therapies and/ or targeted therapeutics and/ or AK/ immune therapies, no hormone therapies) per year.
* Counting method: completed systemic/ cytostatic/ targeted therapy per patient (consisting of several cycles or applications, combination therapies count as 1 therapy). For therapies spanning several years, the therapy started in the survey year counts. 1 therapy per patient = 1 therapy line per disease per patient.
* If this threshold is not met, expertise cannot be proven through cooperation (to be proven individually by each treatment centre).
 |  |
| 6.2.5 | Premises Drug oncological therapy (outpatient only)At least 4 treatment places for intravenous tumour therapy and blood transfusions in a separate room. |  |
| 6.2.6 | Basic diagnostics laboratoryBasic diagnostics including emergency laboratory during working hours must be possible. If external, proof of cooperation agreement. |  |
| 6.2.7 | Basic diagnostics Imaging* 24-hour daily access to sonographic diagnostics.
* 24-hour daily access to radiological emergency diagnostics incl. CT.
* Availability of MRI diagnostics (proof via a cooperation agreement if necessary).
 |  |
| 6.2.8 | a) Uniform standardised schemes for systemic therapies at the centre* The creation/ modification of existing treatment regimens must be subject to regulated approval.
* LL-appropriate antiemetics should be included in the treatment plans.

In the case of highly emetogenic/ moderate emetogenic therapies in particular, the guideline-compliant antiemetic prophylaxis and therapy should be included in the treatment plan: <http://www.leitlinienprogramm-onkologie.de/leitlinien/supportive-therapie/>, Tab. 33.* The pharmacists' expertise can be sought before approving or changing the treatment regimens.
* The treatment regimens must be protected against unintentional changes.
* The treatment regimes are comparable between the outpatient and inpatient units.

 b) Individual therapy plan* Every systemic therapy plan must be based on a therapy scheme.
* The treatment plan must be reviewed and approved.

 c) Release/ administration of the therapyThe therapy must be checked on the day of application, released for the patient and the administration including the time documented. |  |
| 6.2.9 | Cytostatic preparation* Production takes place in a pharmacy in compliance with the legal requirements (including AMG, GMP, GCP, Eudralex (Vol. 10)). If this is not part of the organisation, a supply contract must be concluded.
* Consultation with the pharmacy must be possible during the time the therapy is being administered. 24-hour on-call service required for inpatients.
* Process descriptions for production must be drawn up.
 |  |
| 6.2.10 | Process descriptions* The delegation of medical tasks to nursing staff (e.g. application of cytostatics) must be described.
* The procedure for drug-based oncological therapy must be described for all phases (start of therapy, implementation of therapy and completion of therapy).
* Guideline-compliant supportive measures must be described for the individual therapy concepts and documented in detail for each patient.
 |  |
| 6.2.11 | Standards Concomitant and secondary diseasesFor the prophylaxis/ therapy of concomitant and secondary diseases,* in particular the treatment of extravasations (extravasation set and SOP), infections, thromboembolic complications, allergic reactions and procedures for fever in neutropenia
* and side effect management for immunological and targeted therapies (e.g. osteoprotection with bisphosphonates, RANK ligand-AK, dental/ maxillofacial surgical examination before starting therapy),
* standards must be drawn up and the training for doctors and nursing staff must be documented (protocol).
 |  |
| 6.2.12 | Emergency treatment* Availability of emergency equipment and written emergency plan.
* Annual training of the medical staff of the treatment centre must be documented (content e.g. allergic shock, resuscitation, etc.). The training records must be documented (training records with attendance for the last 12 months).
 |  |
| 6.2.13 | Case-related information/ dialogue with patients in accordance with the participatory decision-making modelWith regard to diagnosis and treatment planning, sufficient information must be provided and a discussion must be held. This includes, among other things* Opportunities and risks of the therapy.
* Presentation of alternative treatment concepts (including palliation where appropriate).
* Offer and mediation of second opinions.
* Final meetings as standard.
* Written patient information (information sheet) on immunological/ targeted therapies and vaccination recommendations for immunosuppression, among other things, should be given to the patient.

 Patient-related discussions must be documented in medical reports or other protocols/ records. |  |
| 6.2.14 | Information on therapy implementation/ planningAfter each application of systemic therapy, the patient and/ or the doctor providing further treatment receive information about the current status of therapy and further planning (blood tests, etc.), e.g. via a follow-up care/ therapy pass. Discharge letter After completion of systemic therapy (last application) and/ or in the event of a change in therapy and/ or after final staging/ cancellation of therapy, the continuing or co-treating doctor will receive the final discharge letter within 7 days. |  |
| 6.2.15 | Induction training for new employeesA systematic, recorded induction for new employees must be ensured, which imparts knowledge of the centre in relation to the respective area of activity.This familiarisation must take place within 3 months of the start of employment.Proof of implementation of the induction concept must be provided (submission of lists of newly hired employees from the last 12 months). |  |
| 6.2.16 | Continuing training * A qualification plan for the medical and nursing staff must be submitted in which the qualifications planned for a one-year period are presented.
* At least 1 specific further education/ training course per employee per year (at least 1 day per year), provided that the employee performs quality-relevant activities for the Centre for Haematological Neoplasia.
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**7. Radio-oncology**

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| **Section** | **Requirements** | **Explanatory remarks by the 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 cross-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 per audit year (goal: no multiple presentations or on-site inspections within one audit year). The "Catalogue of Requirements Radio-Oncology" therefore constitutes an annex to this Catalogue of Requirements. Download cross-organ "Catalogue of Requirements Radio-oncology" on [www.ecc-cert.org](file:///C%3A%5CUsers%5Cc.odenwald%5CDownloads%5Cwww.ecc-cert.org) and [www.onkozert.de](file:///C%3A%5CUsers%5Cc.odenwald%5CDownloads%5Cwww.onkozert.de). |  |

**8. Pathology**

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| **Section** | **Requirements** | **Explanatory remarks by the 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 cross-organ manner. Independently of the number of Organ Cancer Centres/ Modules, which work with a pathology, this "Catalogue of Requirements Pathology" is only to be processed once and also only updated once per audit year (goal: no multiple presentations or on-site inspections within one audit year). The "Catalogue of Requirements Pathology" therefore constitutes an annex to this Catalogue of Requirements. Download cross-organ "Catalogue of Requirements Pathology" on [www.ecc-cert.org](file:///C%3A%5CUsers%5Cc.odenwald%5CDownloads%5Cwww.ecc-cert.org) and [www.onkozert.de](file:///C%3A%5CUsers%5Cc.odenwald%5CDownloads%5Cwww.onkozert.de). |  |
| 8.1 | In particular, successful participation in round robin tests (see CR Pathology Appendix 1) on flow cytometry and cytomorphology should be demonstrated. |  |

**9. Palliative care and hospice work**

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| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 9.1 | Compared to other tumour entities, patients with a haematological neoplasia that cannot be cured by definition can have a significantly longer life expectancy. The timing of information about palliative medical support services should therefore be based on the needs of the patient in question. * Cooperation agreements with service providers of specialised inpatient and outpatient palliative care and inpatient hospices must be demonstrated. Regional concepts for the integration of palliative care must be described on the basis of the treatment pathway for patients and relatives from the S3 guideline on palliative medicine (Fig. 1, page 47), naming all parties involved.
* A doctor with additional training in palliative medicine must be available for consultations and tumour boards.
* The group of patients with incurable haematological neoplasia must be informed about palliative medical support services at an early stage (SOP).
* To identify the need for treatment, it is necessary to carry out a screening to record symptoms and stress (see S3 guideline on palliative care) (e.g. MIDOS or IPOS).
* Access to palliative care can be offered in parallel with tumour-specific therapy. The procedure in the centre must be described in an SOP.
* The number of primary cases with a complex stress situation (positive screening result) must be documented.
 |  |
| 9.2 | Supportive therapy and symptom relief in the palliative situation* The options for supportive/ palliative inpatient therapy must be described (process description/ algorithm)
* A pain therapist must be available. The process for pain therapy (algorithm) must be described and documented cases must be provided for the period under review.
* Access to nutritional counselling must be described and documented for the period under review.
* Access to psycho-oncological and psychosocial care as well as pastoral care must be described.
* In the case of execution via co-operation partners, a co-operation agreement must be concluded for the above requirements.
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**10. Tumour documentation / Outcome quality**

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| **Section** | **Requirements** | **Explanatory remarks by the Cancer Centre** |
| 10.1 | Tumour documentation system* At the time of initial certification, there must be tumour documentation containing the patient data for a period of at least 3 months.
* Patients with haematological neoplasms must be recorded in a tumour documentation system.

 Name of the tumour documentation system in the cancer registry and/ or centre A dataset in accordance with the Uniform Oncological Basic Dataset and its modules of the Association of German Tumour Centres (ADT) and the Association of Epidemiological Cancer Registries in Germany (GEKID) must be used. The centre must ensure that data is transferred to the responsible cancer registry in a timely manner. Any existing state laws on reporting deadlines must be observed. |  |
| 10.2 | Period covered by the dataThe full data are to be presented for the respective last calendar year. |  |
| 10.3 | Cooperation with cancer registry* Proof of cooperation with the responsible 65c cancer registry must be provided on the basis of the cooperation agreement ([www.tumorzentren.de](file:///C%3A%5CUsers%5Cc.odenwald%5CDownloads%5Cwww.tumorzentren.de)).
* The data must be continuously and completely transmitted to the cancer registry.
* The presentation of the key data sheet and the quality of results should be guaranteed via the cancer registry, insofar as this information relates to cancer registration.
* Parallel systems should be avoided.
* As long as the responsible cancer registry cannot meet the requirements, the centre must use supplementary or alternative solutions. The centre is responsible in the event of a non-functioning external solution.
 |  |
| 10.4 | Documentation officerAt least 1 documentation officer must be appointed who is responsible for tumour documentation.Name/ Function: The documentation officer is responsible for the following tasks:* Ensuring and monitoring the timely, complete, comprehensive and correct transmission and quality of the patient data relevant for certification by all co-operation partners to the cancer registry.
* Motivation for cross-sectoral cooperation between the participating specialities in the cancer registry (pathological findings, radiotherapy and drug treatments).
* Ensuring and monitoring the timely, complete and correct recording of patient data.
* Qualification and support of data entry personnel.
* Regular analyses of the evaluations, especially over time.
 |  |
| 10.5 | Provision of resourcesThe necessary personnel capacity should be provided to carry out the documentation tasks and to record the data (for instance 0.5 full-time position for 200 primary cases and 0.1 full-time position for 200 aftercare cases). |  |
| 10.6 | The following selection options must at least be possible in the tumour documentation system:* Vintages
* TNM classification or comparable classification
* Forms of therapy (radiotherapy, immunotherapy, chemotherapy)
* Date of recurrence
* Deaths
* Follow-up status (last update)
 |  |
| 10.7 | Tumour-specific indicators for outcome qualityKaplan-Meier curves:* Overall survival (OAS) for all patients in subgroups by stage
* Progression-free survival (PFS) for all patients and for subgroups
* Survival from progression (PPS)

 Each Kaplan-Meier curve also includes a table with patient numbers and survival data. |  |
| 10.8 | Analysing the data* It must be possible to present the quality of results (above point) for recertification.
* Data in the tumour documentation system must be evaluated at least once a year according to the relevant key figures.
* If a benchmarking/ annual report is offered, the results of the benchmarking must be included in the analysis.
* The discussion of the results must be interdisciplinary; if regional or supra-regional networks exist, they must be involved.
 |  |
| 10.9 | Follow-up recordingDescribe how the follow-up data is obtained and what the current follow-up status is.Functioning cancer registries represent the follow-up status.Where this is not possible, a regional solution is being worked on together with the centres, the ADT, the DKG and the respective government authorities. The follow-up status includes* Progression (local recurrence, regional lymph node recurrence if applicable, distant metastases, at least the first progression in each case)
* Secondary malignancies
* Deaths
* lives at the current address
* Cessation of follow-up (e.g. moving out of the catchment area, federal state)
 |  |

**Data sheet**

A structured EXCEL Data Sheet (= Excel template) is available to Centres to record the indicators and data on outcome quality. This EXCEL Data Sheet (=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 this Data Sheet made available by OnkoZert. No changes may be made to the Data Sheet.

The Data Sheet can be downloaded from <http://ecc-cert.org/> and [www.onkozert.de](http://www.onkozert.de/).