FAQs

Catalogue of Requirements for the for Haematological Neoplasms

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

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

Version FAQ and Catalogue of Requirements (CR)

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The FAQs listed in this document are continuously checked to ensure that they are up to date and adapted in the event of changes to the Technical and Medical Requirements.

Overview of FAQs

Catalogue of Requirements

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Catalouge of Requirement for Outpatient Internal Oncology

Section CR	Requirement		Last update
C Basic requirements for oncological drug therapy	C13	Cytostatic preparation	30.07.2024

Indicator Sheet (=Excel-Template)

Indicator		Last update
2	Number of complex diagnostics for myeloid and lymphatic neoplasms (procedures analogous to OPS: 1-941)	31.08.2022
3	Autologous stem cell transplantation	31.08.2022
4	Allogeneic stem cell transplantation	31.08.2022
7	Transplantation meeting	02.10.2023
11	Number of highly complex and intensive block chemotherapy	31.08.2022
13	Hepatitis and HIV serology before starting therapy	12.09.2024
15	R-CHOP with initial diagnosis ≤ 80 years and curative treatment intention	12.09.2024

FAQ's - Catalouge of Requirement Haematological Neoplasms

1. Structure of the network

Section	Requirements	Explanations of the centre	
1.1.4	If stem cell transplantation 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	FAQ (11 DEC 2019) Do both co-operation partners, maxillofacial surgery and dentistry, have to be present or is one of the two sufficient? Answer: Both co-operation partners (maxillofacial surgery and dentistry) are required.	

1.2 Interdisciplinary cooperation

Section	Requirements	Explanations of the centre	
1.2.1	Number of patient cases The centre must treat 75 patients per year with a diagnosis of haematological neoplasms. 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 Neoplasms 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 Definition of primary case (subset of patient cases): • Patients with initial illness	<u>FAQ (26/08/2019)</u> Why are the minimum number of cases in the centres for haematological neoplasms "patient cases" and not "primary cases" as usual in the certification system? Answer: Patients with haematological neoplasms are those who present to the centre for the first time. Both patients with a first diagnosis and patients with a recurrence can be counted as a patient case. This makes it possible for patients who received their initial treatment outside the centre to be counted towards certification. The time of first presentation at the centre and not the time of diagnosis is defined as the counting time. The reason for this definition is that the diagnosis of patients with haematological neoplasms (e.g. watch+wait patients or progressive courses) may have been made several years ago and the patients should be counted for the calendar year of their first presentation at the centre. <u>FAQ (31/08/2022)</u> A patient comes to the centre for further treatment of his initial diagnosis. Can this patient now be counted as a primary case? Answer: If a patient only presents to the centre for later treatment steps as part of the treatment of the primary disease (external pre-treatment), this can also be counted as a primary case. This also applies analogously to recurrences and pro-gress (here then counted as a patient case).	

1.2 Interdisciplinary cooperation

Section	Requirements	Explanations of the centre	
1.2.3.a	Interdisciplinary tumour board Cycle A tumour board must be held at least once a week. Participants (at specialist level): Haematology and oncology, radiology, radio-oncology, pathology Participation depending on the issue: e.g. surgical disciplines, nuclear medicine, nephrology, palliative medicine, oncological care Patient presentation: • All patients with Hodgkin's lymphoma, non-Hodgkin's lymphoma, Burkitt's ALL, Burkitt's lymphoma or plasma cell neoplasms must be presented pre-therapeutically (exception: emergency therapy initiation). • Recurrent/ refractory patients with Hodgkin's lymphoma, non-Hodgkin's lymphoma, Burkitt's ALL, Burkitt's lymphoma or plasma cell neoplasms as well as other complex cases with haematological neoplasms should be presented as required. Extent of primary cases with Hodgkin's lymphoma, non-Hodgkin's lymphoma, Burkitt's ALL, Burkitt's lymphoma or plasma cell neoplasia discussed: ≥95%	FAQ (31/08/2022) Which patients must be presented at the tumour board? Answer: Patients (= patients presenting to the centre for the first time) with Hodgkin's lymphoma, non-Hodgkin's lymphoma, Burkitt's ALL, Burkitt's lymphoma or plasma cell neoplasia must be presented pre-therapeutically at the tumour board. Recurrent or refractory patients with Hodgkin's lymphoma, non-Hodgkin's lymphoma, Burkitt's ALL, Burkitt's lymphoma or plasma cell neoplasia who have already been presented at the tumour board during their previous treatment should only be discussed again at the tumour board if the new treatment situation requires an interdisciplinary exchange. Other complex cases with haematological neoplasms of the German Cancer Societymust also be presented to the tumour board if there is a need for interdisciplinary discussion.	
1.2.6	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	FAQ (14/07/2020) Can you refer directly to Onkopedia, or do you have to create your own documents for the centre from Onkopedia? Answer: The content of guidelines such as Onkopedia must be transferred, i.e. processed in the sense of a sensible structure and integration into the centre's processes by means of an SOP. This can also include references to existing guidelines. However, a reference alone does not replace an SOP. Responsibilities in particular must be regulated in the SOP and cannot be replaced by a reference.	

	neurological symptoms, an SOP "for treatment must be drawn up within 24 hours of the suspected diagnosis".		

1.2 Interdisciplinary cooperation

Section	Requirements	Explanations of the centre	
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 Neoplasms 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 The results of the quality circle must be recorded.	FAQ (31/08/2022) Can quality circles of the Oncology Centre also be counted for the Centre for Haematological Neoplasms? Answer: No, not in general. Only subject-specific quality circles may be counted, i.e. relating to Haematological Neoplasms. This must be stated in the protocol/agenda.	

1.4 Psycho-oncology

Section	Requirements	Explanations of the centre	
1.4.2	Offer and access Each 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 evaluation To 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 counselling Psycho-oncological care, in particular for patients with excessive stress in the distress screening, must be presented.	FAQ (28/08/2023) How should the proportion of patients with excessive distress in distress screening and further psycho-oncological care be presented? Answer: It should be shown how many screened patients had an above-threshold test. The processes of psycho-oncological care should be described; the number of counselling sessions carried out should be recorded. See separate document FAQ Distress-Scree-ning. FAQ (12/09/2024) How should the proportion of patients with excessive distress in distress screening and further psycho-oncological care be presented? Answer:	

1.4 Psycho-oncology

		It should be shown how many screened patients had an above-threshold test. The processes of psycho-oncological care should be described; the number of counselling sessions carried out should be maintained. the.	

1.6. Patient participation

1.6.5	Event for Pat. The Centre for Haematological Neoplasms 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.	FAQ (12/09/2024) How can the centre prove the exclusion of direct influence by industry representatives? Answer: Proof can be provided e.g. via internal compliance rules or alternatively via a self-disclosure by the centre. In this, the centre should provide information on free access to the event, excluding the industry exhibition/information stands and remarks on contact between industry representatives and patrons.	

1.7 Study management

Section	Requirements	Explanations of the centre	
1.7.2	Study representative The physician 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.	FAQ (14/07/2020) Can the requirements according to section 1.7 of the Catalouge of Requirement be considered covered by a successful certification as a study centre for haematological and oncological diseases according to the criteria of the DGHO? Answer: It can be assumed that certified DGHO study centres fulfil all criteria of the CR, particularly with regard to personnel requirements. Reference can be made to documents (e.g. SOPs) that have already been created as part of DGHO certification. The implementation of the requirements for study management and integration into the network must be checked by the auditors on site. For this purpose, it is necessary that section 1.7 must be completed. For the personnel requirements in section. 1.7.2 and 1.7.3, it is sufficient to state only the name of the study doctor or study authorisation if a DGHO certificate is available.	
1.7.3	Study Assistance - Qualification Vocational training Specialised medical training (e.g. MTA, healthcare/nursing assistant, medical assistant) Education Proof of specific training for the study assistant function must be provided (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, the investigator/student representative has to report the qualification deficits. pensate.		
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.	FAQ (31/08/2022) Can negatively screened study patients be counted? Answer Patients who have signed a informed consent form for screening for study participation can be counted for the numerator of the respective study indicator, even if the results of screening examinations carried out with special diagnostics (no routine diagnostics) do not allow the patients to participate in the study. FAQ (28/08/2023) Can patients referred to a Centre for Personal-ised Medicine (CPM) for the purpose of com-plex diagnostics, interdisciplinary consultation and individual therapy recommendations who participate in a study there be counted towards the study quota of the sending centre?	

		Answer: Yes, in this case the study inclusion can be counted by both the sending centre and the CPM. The other requirements for study inclu-sion according to the survey form will apply. <u>FAQ (12/09/2024)</u> Can patients referred to a Centre for Personalised Medicine (ZPM) for the purpose of complex diagnostics, interdisciplinary consultation and individual therapy recommendations who participate in a study there be counted towards the study rate of the sending centre? Answer: Yes, in this case the study inclusion can be counted by both the sending centre and the ZPM. The other requirements for study admissions apply as per according to the Catalouge of Requirement.	

2.2 Diagnostics

2.2.1. a	Haematology-oncology laboratory:
	Cytomorphology and flow cytometry
	The 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.
	• 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.
		FAQ (31/08/2022)
		If cytomorphology is performed in the evening, must the result also be available on the day of collection?
		
		Answer:
		In urgent cases, the cytomorphology result must be available within a few hours. If the sample is taken late in the evening, for example, a result during the night (and therefore formally the following day) would also be sufficient.	

6.1 Haematology and medical oncology

Section	Requirements	Explanations of the centre	
6.1.3	Availability Specialist in haematology and oncology in the area 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.	FAQ (12/09/2024) Can haematology and oncology specialists who are employed in the Medical Care Centre be counted as part of the staff positions of the department providing the bed? Answer: No, the full time positions cannot be counted. The positions must be itemised, the positions must be provided separately in the department providing the bed.	
6.1.6.a	Stem cell transplantation • [...] For patients with acute leukaemia <70 years of age, HLA typing and presentation at the Bone marrow transplantation (BMT) conference at the start of induction chemotherapy must be ensured together with the cooperation partner for stem cell transplantation.	FAQ (26/08/2019) Do patients with acute leukaemia <70 years of age have to be presented at the KMT conference before induction chemotherapy is started? Answer: No. The presentation at the BMT conference can take place during the ongoing induction chemotherapy.	
6.1.6.e	Nursing staff • Staffing for allogeneic stem cell transplantation corresponding to at least one intermediate care unit.	FAQ (26/08/2019) Which care key applies to an intermediate care ward? Answer: In accordance with the "Recommendations on the equipment and structure of intermediate care units" (publication 03/2017) of the German Interdisciplinary Association for Intensive Care and Emergency Medicine, a nursing ratio of at least 1:4 applies.	

6.2 Organ-specific oncological systemic therapy

Section	Requirements	Explanations of the centre	
6.2.2	Implementation of drug-based tumour therapy (e.g. chemotherapy, Antibody 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.	FAQ (26/08/2019) What is meant by "implementation of drug-based tumour therapy"? Answer: The implementation of drug therapy includes the indication, determination of the therapy regimen, taking into account concomitant diseases, any dosage adjustments during the course of treatment and the monitoring of administration, including any complications. This entire process is the responsibility of a specialist in internal medicine and haematology and oncology. The administration of drug therapy can be delegated, for example to physicians in further training or in accordance with section 6.2.3. trained nursing staff.	

6.2.4	Case numbers per treatment unit • At least 200 drug-based tumour therapies (cytostatic therapies and/ or targeted therapeutics and/ or antibody/ 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).	FAQ (12/09/2024) How is the payment method of a "completed systemic/cytostatic/targeted therapy" defined? Answer: "Completed" also includes the start of therapy, e.g. if this is continued in the outpatient clinic or in the outpatient clinic of a co-operation partner.	

9. Palliative care and hospice work

Section	Requirements	Explanations of the centre	
9.1	Compared to other tumour entities, patients with a haematological neoplasms 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.	FAQ (26/08/2019) When should patients with an incurable haematological neoplasm be informed about palliative care support services? Answer: Compared to other entities, patients with a Haematological Neoplasms that cannot be cured by definition may have a significantly longer life expectancy. The timing of information about palliative medical support should therefore be based on the needs of the patient in question.	

10. tumour documentation / quality of results

Section	Requirements	Explanations of the centre
10.3	Cooperation with cancer registry • Cooperation with the responsible §65c cancer registry must be verified on the basis of the cooperation agreement Link Tumor- zentren.de • [...]	FAQ (14.05.2024) Must the Association of German Tumour Centres (ADT) model cooperation agreement be used? Answer: The use of the cooperation agreement is not mandatory.

FAQ's - Catalouge of Requirement Outpatient Internal Oncology

C) Basic requirements

oncological drug therapy

Section	Requirements	Explanations of the centre	
C13	Cytostatic preparation • Production takes place in a pharmacy in compliance with the legal requirements (e.g. AMG, GMP, GCP, Eudralex (Vol. 10)). If this is not part of the facility, a supply contract must be concluded. • Consultation with the pharmacy must be possible during the period in which the therapy is being administered. • Process descriptions for production must be drawn up.	FAQ (30/07/2024) As the term "supply contract" is a fixed term for contracts between pharmacies and inpatient facilities such as hospitals or nursing homes, outpatient treatment requires an agreement that must be documented in writing.	

FAQ's - Data Sheet Haematological Neoplasms

2	Number of complex diagnoses in myeloid and lymphatic neoplasms	Nominator	Number of complex diagnostics for myeloid and lymphatic neoplasms (procedures analogous to OPS: 1-941)	FAQ (14/07/2020) Can external findings also be taken into account? Answer: Yes. FAQ (31/08/2022) Are patients or procedures recorded for this indicator? Answer: The indicator shows all block chemotherapy performed on patients at the centre (according to the ICD-10 list) in the calendar year, regardless of whether it is a patient case or a primary case. Multiple counts are possible if a pat. has received several block chemotherapies.
		Denominator	-----	
		target value	No target value	
3	Autologous stem cell transplants	Nominator	Autologous stem cell transplantations (OPS: 5-411.0, 8-805.0) (performed at the centre's clinical sites)	FAQ (31/08/2022) Does the numerator refer exclusively to patient cases or are all ICD-10 diagnoses taken into account here? Answer: The expertise of the centre is recorded in indicators 3 and 4, i.e. all stem cell transplants with the specified OPS codes in the indicator year may be counted, regardless of diagnosis and case status. Multiple counts are possible. If a centre does not carry out any stem cell transplants at the clinical sites, a "0" must be entered in the numerator.
4	Allogeneic stem cell transplantation	Nominator	Allogeneic stem cell transplantations (OPS: 5-411.2, 5-411.3, 5-411.4, 5-411.5, 8-805.2, 8-805.3, 8-805.4 or 8-805.5) (performed at the clinical sites of the centre)	

FAQ's - Data Sheet Haematological Neoplasms

7	Transplantation meeting (for allogeneic transplantation at their own clinical site, included in 6)	Nominator	Patients of the denominator with transplatation meeting within three weeks of initial or recurrent diagnosis	FAQ (31/08/2022) Does indicator 7 only include AML and ALL or does Burkitt's lymphoma/Burkitt's ALL also count towards the indicator? Answer: AML and ALL are recorded in the denominator (even if the indication may also be given for other haematological neoplasms) FAQ (02.10.2023) Which diagnoses fall under the definition of "acute leukaemia" in the denominator? Answer: In the denominator, only the diagnoses ALL and AML (C91.0-, C91.5-, C91.8-, C92.0-, C92.3-, C92.4-, C92.5-, C92.6-, C92.8-, C93.0-, C94.0, C94.2-, C94.4-, C95.0-) be recorded.
		Denominator	Patients cases with acute leukaemia < 70 years of age	
		target value	≥ 95%	
11	Number of highly complex and intensive block chemotherapy treatments in patients with haematological neoplasms	Nominator	Number of highly complex and intensive block chemotherapy treatments in patients with haematological neoplasms (according to basic data and OPS 8-544)	FAQ (31/08/2022) How is the counting time defined? Answer: All procedures that were completed in the indicator year may be counted (no counting of patients, no restriction to patient cases).

FAQ's - Data Sheet Haematological Neoplasms

13	Hepatitis and HIV serology before starting therapy	Nominator	Patients of the denominator with hepatitis B, C and HIV serology before systemic therapy	FAQ (14/07/2020) Can patients who refuse to give their consent to the HIV status survey also be counted? Answer: Patients with both HIV and hepatitis B/C serology must be included in the numerator. It is not possible to count patients who refuse to consent to their HIV status being recorded. This circumstance should be documented and, if necessary, addressed in the audit. FAQ (31/08/2022) Can external findings or findings from longer ago also be taken into account? Answer: External findings can be used. In general, findings must not be older than 6 months in order to be counted. FAQ (31/08/2022) Is it only permissible for no system therapies to have been provided in the same centre before the serologies or may no system therapies have been provided in external facilities beforehand? Answer: For reasons of operationalisability, patients with first systemic therapy in their own centre are counted here. Externally administered systemic therapies prior to presentation at the centre do not count. FAQ (31/08/2022) Indicator 16 contains a "Hepatitis and HIV serology before the start of therapy" is required. Does the serology also have to be carried out before the pre-phase therapy? Answer:
		Denominator	'Patient cases with haematological neoplasmsand systemic therapy	
		Target value	≥ 70%	

				Serology does not have to be carried out before the start of pre-phase therapy. FAQ (12/09/2024) Which patient cases may be counted in the denominator? Answer: Patients with a Haematological Neoplasms and a systemic antineoplastic therapy. therapy are to be counted in the denominator.
15	R-CHOP with initial diagnosis ≤ 80 years and curative treatment intention	Nominator	Patients of the denominator with immunochemotherapy with R- CHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, prednisone) or a protocol similar to R-CHOP-	FAQ (12/09/2024) What is meant by R-CHOP-like protocol? Answer: R-CHOP-like = rituximab; cyclophosphamide; doxorubicin, other anthracyclines, mitoxanthron; vincristine, polatuzumab vedotin; prednisone, other glucocorticosteroids; etoposide
		Denominator	Patients with first diagnosis of diffuse large B-cell lymphoma (DLBCL) (ICD-10 C82.4, C83.3, C83.8, C85.2) ≤ 80 years and curative treatment intention	