**Catalogue of Requirements**

**Visceral Oncology Centre**

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

**Chairs of the Certification Committee:** Prof. Dr. T. Seufferlein, Prof. Dr. S. Post

**Prepared by the DKG Certification Committee Visceral Oncology Centre**

**Expert groups involved (in alphabetical order)**

ABO Working Group for Imaging in Oncology

ADDZ Working Group of DKG-certified Colorectal Cancer Centres

AdP Working Group of Pancreatectomy Patients

ADT Association of German Tumour Centres

AIO Working Group for Internal Oncology

AOP Working Group for Oncological Pathology

APM Working Group for Palliative Medicine

ARO Working Group for Radio-Oncology

ASO Working Group for Social Work in Oncology

ASORS Working Group for Supportive and Rehabilitation Oncology

AUO Working Group for Radio-Oncology

BDI Professional Association of German Internists

BDP Association of German Pathologists

BNG Professional Association of Practice-based Gastro-enterologists Germany

BNHO Association of Practice-based Haematologists and Oncologists in Germany

BVDST Professional Association of German Radiotherapists

BVGD Professional Association of Gastro-enterologists Germany

CAO Surgical Working Group for Oncology

CAO-V Surgical Working Group for Oncology - Visceral Surgery

DeGIR German Society for Interventional Radiology

DEGRO German Society of Radio-Oncology

DGAV German Society for General and Visceral Surgery

DGHO German Association of Haematology and Oncology

DGN German Society of Nuclear Medicine

DGP German Society of Palliative Medicine

DGP German Society of Pathology

DGVS German Society for Digestive and Metabolic Diseases

DRG German X-Ray Society

DVSG German Association of Social Work in Health Care

German ILCO

KOK Conference on Oncological and Paediatric Oncological Care

PRIO Working Group for Prevention and Integrative Medicine in Oncology

PSO Working Group for Psycho-Oncology

Joint Project Familial Colorectal Cancer

**Entry into force on 20 September 2019**

Changes to the version dated 22 November 2019: Compared to the version dated 20 September 2019, in chapters 1.2.0 and 5.2.4 the ICD codes for independent gastric cancer centres without a certified esophageal cancer centres have been added.

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| The following were incorporated: | * S3 Guidelines "Diagnosis and treatment of adenocarcinomas of the stomach and the esophagogastric junction" * S3 Guidelines "Exocrine pancreatic cancer" * S3 Guidelines "Diagnosis and treatment of colorectal cancer" * S3 Guidelines "Diagnosis and treatment of the hepatocellular carcinoma" * S3 Guidelines Diagnosis and treatment of squamous cell carcinomas and esophageal adenocarcinomas |

The Catalogue of Requirements is based on the TNM classification of malignant tumours, 8th edition 2017, the ICD classification ICD-10-GM 2019 (DIMDI) and the OPS classification OPS 2019 (DIMDI).

**Information on the Visceral Oncology Centre**

**Centre’s area of application:**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  | Colorectal |  | Pancreas |  | Stomach |
|  |  |  |  |  |  |  |
|  |  | Liver (LCC) |  | Esophagus |  |  |

|  |  |
| --- | --- |
| Clinical site (clinic/hospital) |  |
| Director of the Centre |  |
| Centre Coordinator |  |

**QM system certification**

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

A certified QM system is not mandatory within the framework of DKG certification but should, however, be available.

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| QM standard |  | ISO 9001 |  | KTQ |
|  |  |  |  |  |
|  |  | Joint Commission |  | proCum Cert |

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| --- | --- |
| Certification body QM |  |

**Network/Main cooperation partners**

The Centre's cooperation partners are registered in a master data sheet with OnkoZert. The details in the master data sheet are published on [www.oncomap.de](http://www.oncomap.de/). Any new or no longer valid cooperation is to be notified immediately to OnkoZert, outside the certification period, too. Other updates (e.g. changes to management, contact data) are to be indicated in the corrected master data sheet in the run-up to the annual surveillance audit. The master data sheet with the registered cooperation partners can be requested from OnkoZert as a file.

**Preparation / Update**

The electronically generated Catalogue of Requirements serves as the basis for the certification of the Centre. The details provided there have been checked for correctness and completeness.

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

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| Preparation/update date of the Catalogue of Requirements |  |

**Prologue**

In the Certified Centres interdisciplinary, inter-professional and trans-sectoral networks are established that cover the entire chain of care from the patient angle.[[1]](#footnote-1) The contents of the evidence-based Guidelines are the basis for clinical work. A series of Visceral-oncological Guidelines, with the related quality indicators, have been published within the framework of the [Oncology Guidelines Programme](http://www.leitlinienprogramm-onkologie.de/). Based on these Guidelines the Certification Committee (see cover) has drawn up the contents that are used in the Visceral Oncology Centres.

In order to facilitate practical implementation and to reduce the number of Catalogues of Requirements and audit procedures, the individual tumour entities (Definition "Area of application" on page 2) have been grouped together under the umbrella "Visceral Oncology Centre" (VC). In line with their specific specialisation and expertise, the Centres can lay down their area of application themselves.

A VC fulfils at least the requirements (in line with the definition "area of application" on page 2) for:

1 Colorectal Cancer Centre + 1 additional tumour entity or for 3 of the 4 modules (liver, stomach, pancreas and esophagus)

Aside from this, the certification of an independent Colorectal Cancer Centre is still possible.

Certification is undertaken, irrespective of the number of modules selected, during the audit. It is possible to change the area of application at a later date. The area of application is indicated on the certificate.

This Catalogue of Requirements (CR) is binding for all audits conducted from 1 January 2020. The changes made to the version valid in the audit year 2019 are highlighted in "turquoise" in this Catalogue of Requirements.

Centres that apply for certification for one Colorectal Cancer Centre plus at least one further tumour entity use this Catalogue of Requirements. Centres that are certified solely as Colorectal Cancer Centres continue to use the organ-specific Catalogue of Requirements for Colorectal Cancer Centres.

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Annexes:

Data sheet – Colorectal

Data sheet – Pancreas

Data sheet – Stomach

Data sheet – Liver

Data sheet – Esophagus

(separate documents in Excel format)

|  |  |
| --- | --- |
| Colour legend | "black" .... relevant for all organs |
|  | only relevant for "colorectal" |
|  | only relevant for "pancreas" |
|  | only relevant for "stomach" |
|  | only relevant for "liver" |
|  | only relevant for "esophagus" |

| 1. General information on the Centre **1.1** **Structure of the network** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks of the Centre |  |
| 1.1.1  - All - | The names of the persons holding the following positions are to be given:   * Director of the Centre (max. 2 directors/Centre, of whom 1 named contact) * Centre Coordinator   Centre Coordinator – tasks   * Coordination 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  - All - | Main cooperation partners and cooperation partners can be part of a clinic or also be independent practices.  Main cooperation partners  Visceral surgery, gastroenterology, radiotherapy, haematology/oncology, pathology, radiology (only LCC: interventional radiology)  Cooperation partners  Psycho-oncology, social work, stomatherapy (only colorectal), nutritional counselling, physiotherapy, genetics, pain therapy and self-help group, palliative medicine, diabetology (only pancreas) |  |  |
| 1.1.3  - All - | Cooperation agreements  A cooperation agreement is to be entered into with cooperating treatment partners. Documentation must be provided that they meet the appropriate Technical and Medical Requirements of the Catalogue of Requirements (not every service provider has to be a cooperation partner as well). The cooperation partners are to be listed in the "master data sheet" (administration by OnkoZert).  If the cooperation partners of a Centre work under a funding body or at a clinical site, written agreements are not necessary (nonetheless the implementation of the following points must be ensured).  The following points are to be regulated:   * Competences and responsibilities * Description of the treatment processes of relevance for the Centre bearing in mind the interfaces * Obligation to implement indicated Guidelines * Description of cooperation on tumour documentation * Declaration of willingness to cooperate on internal/external audits * Undertaking to comply with the relevant DKG criteria and the annual submission of the relevant data * Upholding of medical confidentiality * Participation in continuing education/specialty training programmes and public relations work * Declaration of consent to be publicly identified as part of the Centre (e.g. homepage) * 24/7 reachability of main clinical cooperation partners in VC: surgeons, gastro-enterologists, radio-oncologists, radiologists |  |  |
| - All - | Tumour conference (only to the extent that participation is required under "1.2 Interdisciplinary cooperation")   * Binding participation * Ensuring availability of specialist for the specialty to which binding participation applies * Participation and consensus provisions in the case of more than 1 cooperation partner for each specialty (see also provisions "Interdisciplinary cooperation") |  |  |
| - Liver - | * Visceral Oncology Centres, which do not perform liver transplantations, must document cooperation with one of the transplantation centres recognised by the federal state ministry. * Cooperation is to be documented using concrete patient medical records for each calendar year. * Patients who are eligible for a transplant in line with the recommendation of the tumour conference must be presented in a recognised transplantation centre. |  |  |
| 1.1.4  - All - | Presentation of the Centre  The overall structure of the Centre is to be presented and made public (e.g. Internet). This also encompasses giving the names of all internal/external cooperation partners with the following details:  - Name, address of cooperation partner  - Cooperation partner with tel./email |  |  |
| 1.1.5  - All - | Strategy planning/Reporting  It is recommended to conduct an annual review on the management level in which the following aspects, for instance, are examined:   * Goal definition/assessment, where appropriate new orientation of goals * Consideration of audit results (internal/external) * Human resources for Centre management (Centre Coordinator) * Public relations work/Patient information * Tumour documentation/Outcome quality |  |  |
| ~~1.1.6~~  ~~- All -~~ | ~~Treatment errors~~   * ~~Any treatment errors determined inside and out of court (expert/mediation committee) are to be processed and presented to the certifier in the run-up to certification.~~ * ~~Special attention should be paid to the re/actions of the Centre resulting from these proceedings within the framework of an ensuing certification.~~ * ~~The relevant calendar year is the period covered by the audit.~~ * ~~Non-compliance is deemed to be a deviation.~~   Colour legend: change compared to version of 17 October 2018 |  |  |

| **1.2** **Interdisciplinary cooperation** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks of the Centre |  |
| 1.2.0 | Number of primary cases |  |  |
| - Colorectal -  CR CC 5.2.4 | Surgical expertise Centre   * 30 colon carcinomas * 20 rectal carcinomas   Primary case definition, see last page of this Catalogue of Requirements | Data sheet colorectal (Excel template) |  |
| - Pancreas - | The Centre must treat 25 patients annually with a primary diagnosis of pancreatic cancer (ICD-10 C 25).  Definition:   * Patients and not stays or surgical procedures * Adenocarcinomas, neuroendocrine carcinomas are counted. IPMNs (intraductal papillary mucinous neoplasms) are not counted. * Histological/cytological findings must be available (biopsy or resection) from primary tumour or metastasis with concomitant presence of a pancreatic tumour in medical imaging. * Patient with initial disease * The time of counting is the time of the histological confirmation of diagnosis * Patients, who are only presented for the purposes of seeking a second opinion or for the purposes of consultation, are not included. | Data sheet pancreas (Excel template) |  |
| - Stomach - | The Centre must treat 30 patients annually with a primary diagnosis of an adenocarcinoma of the stomach and of the esophagogastric junction (ICD-10 C, 16.01, 16.1-16.9). If the Centre is not certified as an esophageal cancer centre at the same time, the ICD-10 C 15.2 and 15.5 and 16.022 can be included in the scope of the stomach cancer centre.  Definition:   * Patients and not stays or surgical procedures * Histology / cytology report must be available (biopsy or resection). * Patient with initial disease * The time of counting is the time of the histological confirmation of diagnosis * Patients, who are only presented for the purposes of seeking a second opinion or for the purposes of consultation, are not included.   1 Tumours, whose centre is > 2 cm from the esophagogastric junction, are classified as gastric carcinomas even if the esophagogastric junction is affected.  2 Tumors that involve the esophagogastral junction and their center within the prox. 2 cm of the esophagogastral junction (proportion Siewert type I / Siewert type II) is counted as esophageal carcinoma.  Colour legend: change compared to version of 17 October 2018  Colour legend: change compared to version of 20 September 2019 | Data sheet stomach (Excel template) |  |
| - Liver - | The Centre must treat 30 patients annually with a primary diagnosis of an liver carcinoma (ICD-10: C22.0)  Definition:   * Patients and not stays or surgical procedures * Patient with initial disease (incl. primary M1) * The time of counting is the time of the histological/imaging confirmation of diagnosis * Patients, who are only presented for the purposes of seeking a second opinion or for the purposes of consultation, are not included. | Data sheet liver (Excel template) |  |
| - Esophagus-  röhre -  new | The Centre must treat 40 patients annually with the diagnosis of a high-grade dysplasia (HYIEN, HGD) or an invasive squamous cell carcinoma or an esophageal adenocarcinoma (= Centre cases).  of which at least 20 patients with a primary diagnosis  (ICD-10 C15, 16.02, D00.1 (HGD, HGIEN))  Definition primary diagnosis:   * Patients and not stays or surgical procedures * Patient with initial disease (incl. primary M1) * The time of counting is the time of the histological/imaging confirmation of diagnosis * Patients, who are only presented for the purposes of seeking a second opinion or for the purposes of consultation, are not included.   2 Tumours that affect the esophagogastric junction and whose centre is within the prox. 2 cm of the esophagogastric junction (proportion Siewert type I/Siewert type ll), are counted as esophageal carcinomas. | Data sheet esophagus (Excel template) |  |
| 1.2.1  - All - | Cycle/Participants tumour conference  A tumour conference must be held at least once a week.  For the following specialties participation by specialists in the conference is mandatory:   * Visceral surgery * Gastro-enterology * Radiotherapy * Haematology/Oncology * Pathology * Radiology (LCC: interventional radiology   Metastases:  In the case of organ metastases a surgeon with the corresponding specialisation and specific expertise is to be consulted.  Depending on the indication, other participants (palliative medicine, psycho-oncology, etc.) are to be invited.  If the haematologist/oncologist is unable to attend the conference, he/she may be represented by the specialist responsible for chemotherapy who complies with the requirements in Section 6.2. |  |  |
| 1.2.2  - All - | General requirements tumour conference  Several cooperation partners If several cooperation partners are named for a specialty, then the presence of one representative is sufficient as long as the formalised exchange of information between the partners is in place (e.g. via quality circles).  Independently thereof, each cooperation partner must take part in the tumour conference at least once a month.  Web/online conference  If web conferences 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 conferences with no imaging material are not an option. |  |  |
| 1.2.3  - All - | Indicator Presentation tumour conference   * Pretherapeutic case presentation * Post-operative case presentation   All pretherapeutic/post-operative cases are to be presented at the tumour conference in line with the respective indicator definition. If no presentation is made, clear reasons must be given in the patient’s medical record. | Data sheets (Excel templates) Colorectal / Pancreas / Stomach / Liver / Esophagus |  |
| - Colorectal - | Presentation tumour conference  Patients with a rectal carcinoma should be presented again in the tumour conference after termination of neoadjuvant therapy and in the case of full clinical remission in order to discuss the indication of a Watch &Wait strategy. |  |  |
| 1.2.4  - Colorectal - | Recurrence/metastasis   * Surgical responsibilities for metastasis resection are to be laid down (in particular liver, lung) where appropriate by means of cooperation. * Therapeutic approaches (curative and palliative) for metastasis surgery and radiotherapy (e.g. stereotactic irradiation of brain tumours) are to be laid down in the descriptions of the procedures. * Patients with primary unresectable liver metastasis should be regularly presented during systemic therapy for evaluation in the tumour conference. |  |  |
| 1.2.5  - All - | Demonstration imaging material Patient-related imaging material must be available at the conference and suitable technical equipment must be provided for the presentation of this material. |  |  |
| 1.2.6  - All - | Preparation tumour conference   * The main patient and treatment data are to be compiled in writing beforehand and made available to the participants at the conference. A pre-appraisal of suitable study patients is to be undertaken. * All patients with recurrences and/or metastases, who have entrusted the Centre with their care, are to be presented. |  |  |
| 1.2.7  - All - | Minutes of the tumour conference   * The results of the tumour conference consist, *inter alia*, of a written, interdisciplinary treatment plan ("Minutes tumour conference"). * The minutes of the tumour conference must be available at all times in a secure manner to all main cooperation partners and can, at the same time, constitute the medical report. * The "minutes of the tumour conference" should be automatically generated from the tumour documentation system. * The outcome of the tumour conference is to be recorded in the tumour documentation system. |  |  |
| 1.2.8  - All - | Participation tumour conference as continuing education  For the following functions/professional groups, participation in the tumour conference is to be made possible:   * Assistant staff (MTA, MTRA, ...) from the fields of radiology and radiotherapy * Staff members social services and psycho-oncology * Specialist oncology nurse and at least 2 nurses for each treatment unit * Participation in the tumour conference is recognised as continuing education for the aforementioned functions/professional groups. |  |  |
| 1.2.9  - All - | Therapy deviation   * The therapeutic procedure should be oriented towards the treatment plans or recommendations of the tumour conference. * If any deviations from the original therapy plan or deviations from the Guidelines are observed, they must be recorded and evaluated. Depending on the cause, avoidance measures are to be taken. * If therapy is not started or terminated prematurely at the patient's request (despite an existing indication), this must also be recorded. |  |  |
| 1.2.10  - All - | Morbidity/mortality conference   * The conference can be staged on the same date as the tumour conference. * A list of participants is kept. * Conferences are to be held at least twice a year. * Cases with a special course of the disease or a course that needs to be improved are to be discussed. Patients who died post-surgery/post-intervention must definitely be discussed. * Minutes are to be taken of conferences. |  |  |
| 1.2.11  - All - | Quality circles   * Tasks, circle of participants and contents of the quality circles are to be laid down. * Conferences are to be held at least four times a year. * A list of participants is kept. * The quality circles must produce clear results (actions, decisions) which seem likely to bring about a major further development of/improvement in the Centre. * The outcome of the quality circles is to be recorded.   Possible topics:   * Analysis of outcome quality (benchmarking) * Interdisciplinary continuing education * Interdisciplinary case reviews * Structural improvements to the Centre * Public relations   At the time of initial certification one quality circle must have taken place. |  |  |
| 1.2.12  - All - | Continuing education   * Continuing education events are to be staged for the network of the Visceral Oncology Centre at least twice a year (where appropriate also after the morbidity & mortality conferences/quality circles). * Contents/results and participation are to be recorded. A continuing education plan is to be presented. |  |  |
| 1.2.13  - All - | Events of the Centre  Each main cooperation partner must participate in at least two of the Centre's events. The following are recognised:   * Quality circles * Morbidity/mortality conference * Continuing education |  |  |

| **1.3** **Cooperation referrers and aftercare** | | | |
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| Section | Requirements | Explanatory remarks of the Centre |  |
| 1.3.1  - All - | Cooperating referrers  An 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:  Obligations of the Centre:   * Referrers are entitled to attend the tumour conference when their patients are presented. * Referrers are to be given the opportunity to present patients in the tumour conference. |  |  |
| 1.3.2  - All - | Contacts  The Centre's contacts are to be given to the referrers in line with their function (e.g. telephone number, email). This can be done with the required publication of the cooperation partners. |  |  |
| 1.3.3  - All - | Provision of documents  The co-attending physicians are to be given the following information in a timely manner (individual documents and/or summaries in the medical report):   * Histology * Tumour conference minutes / treatment plan * Surgical report (optional) * Changes to therapy   Timeline for the provision of the necessary information to the co-attending physicians < 2 weeks |  |  |
| 1.3.4  - All - | Feedback system  For the co-attending physicians a written standard operating procedure (SOP) for the recording, processing and feeding back of the general and case-related concerns/questions/complications is to be put in place. |  |  |
| 1.3.5  - All - | Referrer satisfaction survey   * 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  - All - | Continuing education  Events 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** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks of the Centre |  |
| 1.4.1  - All - | Psycho-oncology – qualifications   * Qualified psychologists or * physicians   with a psychotherapeutic specialty training and psycho-oncological continuing education  The following courses are recognised as continuing education/specialty training:  "Specialty training in psychosocial oncology" staged by the Working Group for Psycho-Oncology (PSO) or the German Working Group for Psychosocial Oncology (dapo) or other adequate continuing education with a volume of > 100 teaching units. Proof of competence is to be provided by means of a special training curriculum.  The representatives of other psychosocial professional groups (like qualified paedagogues, social workers, pastoral care etc.) can be accepted on presentation of the above-mentioned psycho-oncological qualifications. For this, a case-by-case examination is required.  The assumption of psycho-oncological tasks by the social services, self-help groups or pastoral care is not sufficient. They supplement psycho-oncological care. |  |  |
| 1.4.2  - All - | Psycho-oncology – 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, screening of mental strain must be undertaken (for instance see S3 Guidelines Psycho-Oncology) and the outcome is to be documented.  Psycho-oncological care is to be documented and evaluated in an ongoing manner using suitable instruments (e.g. Basic Documentation for Psycho-Oncology - PO-BaDo). |  |  |
| - All - | Psycho-oncological care  The number of patients who have taken up psycho-oncological care is to be recorded. | Data sheets (Excel templates) Colorectal / Pancreas / Stomach / Liver / Esophagus |  |
| 1.4.3  - All - | Psycho-oncology resources  At least 1 psycho-oncologist is available to the Centre (name is to be given). |  |  |
| 1.4.4  - All - | Premises  A suitable room is to be provided for psycho-oncological patient consultations. |  |  |
| 1.4.5  - All - | Organisation plan  If psycho-oncological care is provided by external cooperation partners or for several clinical sites and clinic facilities, the performance of tasks is to be laid down in an organisation plan that contains details, *inter alia*, of the availability of resources and local presence. |  |  |
| 1.4.6  - All - | Psycho-oncology – tasks  The psycho-oncological care of patients is to be offered at all stages of care (diagnosis, inpatient, post-inpatient).  Goals and tasks of care:   * Diagnostic clarification after positive screening * Prevention/treatment of resulting psychosocial problems * Activation of personal coping mechanisms * Maintenance of quality of life * Consideration of social environment * Organisation of further outpatient care through cooperation with outpatient psycho-oncological service providers * Public relations (patient event or the like) |  |  |
| 1.4.7  - All - | The following are also recommended:   * Provision of supervision, initial and continuing education courses for staff * Twice yearly discussions between psycho-oncologists and the nursing and medical areas * Regular written and, where appropriate, oral feedback on psycho-oncological activities to the medical staff (e.g. through a referral report or documentation in the medical record) * Regular participation in ward conferences and tumour conferences * Close cooperation with the social services * Interface/exchange with self-help and pastoral care * The psycho-oncologists should present their work at least twice a year at the tumour conferences. |  |  |
| 1.4.8  - All - | Continuing education/specialty training  At least 1 dedicated continuing education/specialty training session a year for each staff member (at least 1 day a year) |  |  |

| **1.5**  **Social work and rehabilitation** | | | |
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| Section | Requirements | Explanatory remarks of the Centre |  |
| 1.5.1  - All - | Qualifications social services:  Social workers/social pedagogues  Resources:  For patient counselling in the Centre at least 1 full-time staff member is available for 400 counselling sessions for patients of the Centre (= primary cases, secondary metastasis, recurrence). Human resources can be made available centrally, an organisation plan must be available.  Premises:  A suitable room is to be provided for social counselling work. |  |  |
| 1.5.2  - All - | Each patient must be offered the option of counselling by social services at all stages of the disease in a timely manner in the vicinity (proof required). The offer must be made in a low-threshold manner.  The number of patients who received counselling from the social services is to be recorded. | Data sheets (Excel templates) Colorectal / Pancreas / Stomach / Liver / Esophagus |  |
| 1.5.3  - All - | Contents of counselling:   * Identification of social, economic and mental health emergencies * Start of medical rehabilitation measures * Advice on social law and economic issues (e.g. severely disabled persons' legislation, wage replacement benefits, pensions, benefit requirements, co-payments, and many other issues) * Support for submitting applications * Advice on outpatient and inpatient care treatment options and referral to support schemes and specialised services * Support for professional and social reintegration * Cooperation with service funding agencies and service providers * Intervention in emergencies |  |  |
|  | Further tasks:   * Public relations and networking * Participation in ward conferences and tumour conferences, supervision, continuing education * Interdisciplinary cooperation particularly with physicians, nursing staff, physiotherapists, psycho-oncologists, pastoral services, self-help groups *inter alia* * Documentation of activities |  |  |
| 1.5.4  - All - | Care services provided  Social services are to provide information material or a database in which the cooperating bodies (e.g. oncological rehabilitation) and other regular contact points including contact data of contact persons are managed in a transparent and up-to-date manner. These data must be available to all staff members of social services. |  |  |
| 1.5.5  - All - | Continuing education/specialty training  At least 1 dedicated continuing education/specialty training session a year for each staff member (at least 1 day a year) |  |  |
| 1.5.6  - All –  NEW | Choice of rehabilitation facilities tailored to individual patient needs  Patients should be offered an oncological rehab if there is an indication (see also 1.5.4).  Colour legend: change compared to version of 17 October 2018 |  |  |

| **1.6** **Patient involvement** | | | |
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| Section | Requirements | Explanatory remarks of the Centre |  |
| 1.6.1  - All - | Patient surveys:   * At least every 3 years all Centre patients are given the opportunity over a period of at least 3 months to take part in a patient survey. |  |  |
|  | The "return rate patient survey" should be higher than 50%. |  |  |
| 1.6.2  - All - | Evaluation patient survey   * Responsibility for the evaluation is to be specified. * The evaluation must encompass the patients of the Centre. * A recorded evaluation is to be made and presented during the audit. * Actions are to be laid down on the basis of the evaluation. * The evaluation can be considered in connection with a quality circle. |  |  |
| 1.6.3  - All - | Patient information (general)   * The Centre should give a full presentation of itself and its treatment options (e.g. in a brochure, patient folder, homepage). * The names of the cooperation/treatment partners are to be given with details of the contact. A description is to be given of the treatment on offer. * The presented treatment offering must encompass: Rehabilitation/post-hospital rehabilitation, self-help, treatment measures and alternatives * Information provided: for instance patient guidelines and/or S3 Guidelines of the Oncology Guidelines Programme |  |  |
| 1.6.4  - All - | Discharge consultation:  Each patient is given a discharge consultation (short documentation/check list) in which at least the following topics are addressed:   * Therapy planning * Individual aftercare plan (where appropriate handing over of an aftercare pass) |  |  |
| - Liver - | * Information on continued treatment of an HCV/HBV infection in line with S3-LL of the German Society for Digestive and Metabolic Disorders (DGVS) and continuation of other liver-specific treatment methods |  |  |
| - Stomach - | * Information on need for vitamin B12 substitution |  |  |
| - Pancreas - | * Information on possible secondary diseases (e.g. diabetes) and the related risks (e.g. hypoglycaemias) |  |  |
| 1.6.5  - All - | Patient information (case-related):  The patient is given the following documents:   * Medical report / discharge letter (including details tumour conference / treatment plan) * Aftercare plan / aftercare pass * where applicable, study documents   It is recommended that patients are given a central /structured folder for the documents. The procedure for the provision of patient information is to be standardised. |  |  |
| 1.6.6  - All - | Event for patients  The Centre is to stage an information event for patients and/or interested persons at least once a year.  (can be considered together with 1.6.9) |  |  |
| 1.6.7  - All - | Complaint management  An official procedure for complaint management is in place. Patients are given feedback. Complaints are taken into account in the improvement process. |  |  |
| 1.6.8  - All - | Self-help groups  The self-help groups, with which the Cancer Centre actively cooperates, are to be named. If possible, the self-help group should consider the specific needs of visceral oncology patients (keyword - affected by the same condition). |  |  |
| 1.6.9  - All - | Self-help groups  Self-help can be active in the field of patient involvement, psychosocial support and as an interest group. And, where appropriate, in the audit in these areas.  The self-help groups, with which the Cancer Centre actively cooperates, are to be named. Written agreements with the self-help groups are to be entered into which cover the following points:   * Access to self-help groups at all stages of treatment (initial diagnosis, hospitalisation, chemotherapy, ...); * Provision of contact data of self-help groups (e.g. in patient brochures, homepage of the VC) * Options to display information brochures of self-help groups * Regular provision of rooms at the VC for patient consultations * Quality circles with the participation of representatives of psycho-oncology, self-help groups, social services, pastoral care, nursing care and medicine * Personal discussions between the self-help groups and the Centre with a view to jointly staging or mutually agreeing on actions and events. The results of the discussions are to be recorded. * Involvement of medical staff in the events of the self-help group |  |  |

| **1.7** **Study management** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks of the Centre |  |
| 1.7.1  - All - | Access to studies  It must be possible for patients to access studies. The studies conducted at the Centre must be listed and published, for instance on the Centre's homepage (including short description of the study). |  |  |
| 1.7.2  - All - | Study manager  The name of the investigator in charge of the study is to be given.  Study assistance   * The name of a study assistant is to be included in the "study organisation chart" for "each active study unit". * He/she can work in a parallel manner for several "units conducting studies". |  |  |
| 1.7.3  - All - | Study assistance – qualifications  Professional training  Continuing education courses (e.g. MTA, nurse/health care assistant, physician's assistant)  Training  Special training for the study assistance function must be documented (guidance value: several day course).  At the time of initial certification at least one registration for a course must be available. The course is to be completed within one year. During training the investigator / study manager must compensate for qualification deficits. |  |  |
| 1.7.4  - All - | Study assistant - Tasks  The range of tasks is to be laid down in writing (via position/function descriptions) and can encompass, *inter alia*, the following contents:   * Conduct of studies together with the investigator in charge of the studies * Patient care during the study and aftercare * Organisation, coordination of diagnosis, laboratory, sample dispatch and test medication * Collection and documentation of all data of relevance for the studies * Preparation of and support for audits and authority inspections * The activity of the study assistant can be combined with other activities like tumour documentation. |  |  |
| 1.7.5  - All - | Cooperation study assistant – investigator  Direct availability of investigator or study manager for the study assistant is to be ensured (Documentation, for instance, about regular exchange). |  |  |
| 1.7.6  - All - | Proportion study patients  1. Initial certification: At the time of initial certification ≥ 1 patients must have been included in studies (guidance value: ≤ 6 months prior to certification)  2. after 1 year: at least 5% of the primary case number  The requirement applies to each tumour entity. | Data sheets (Excel templates) Colorectal / Pancreas / Stomach / Liver / Esophagus |  |
|  | Only the inclusion of patients in studies with an ethical vote counts as study participation (non-interventional/diagnostic studies and prevention studies are also recognised).  All study patients can be taken into account when calculating the study rate (share study patients based on the Centre's primary case number).  General preconditions for the definition of the study quota:   * Patients can be counted 1x per study, time: date of patient consent. * Patients in a palliative and adjuvant situation can be counted, no limitations regarding stage of disease. * Patients for colorectal prevention studies can be counted. * Patients who are taking part in several studies simultaneously can be counted several times. * Patients in the follow-up of a study are no longer included in the study rate. |  |  |
| 1.7.7  - All - | Standard operating procedures (SOPs): The SOPs including responsibilities are to be laid down for the launch/initiation of new studies and the conduct of studies for each "active unit". This encompasses for instance:   * Selection of new studies including release decision * Internal announcement of new studies (update study list, ...) * Study organisation (special features care study patients, documentation, ...) * Type of announcement of study results (e.g. MA, patients) |  |  |
| 1.7.8  - All - | Study assignment  Before study participation can be recommended to a patient, there must be a patient-based discussion beforehand in the interdisciplinary tumour conference. |  |  |

**List of the studies**

List of studies - colon/rectum 1)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Responsible cooperation partner 2) | | Name of the study | Centre patients | | Patients total | |
| Recruited in 2019 3) | Total recruited  incl. previous years | Recruited in 2019 | Total recruited  incl. previous years |
| !! Details optional !! | | |
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|  | Numerator Indicator No. 6 "Study rate" | |  |  |  |  |

The list of accredited studies that can, therefore, be calculated for the study rate is depicted in [www.studybox.de](http://www.studybox.de/).

List of studies - pancreas 1)

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| --- | --- | --- | --- | --- | --- | --- |
| Responsible cooperation partner 2) | | Name of the study | Centre patients | | Patients total | |
| Recruited in 2019 3) | Total recruited  incl. previous years | Recruited in 2019 | Total recruited  incl. previous years |
| !! Details optional !! | | |
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|  | Numerator Indicator No. 6 "Study rate" | |  |  |  |  |

List of studies - stomach 1)

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| --- | --- | --- | --- | --- | --- | --- |
| Responsible cooperation partner 2) | | Name of the study | Centre patients | | Patients total | |
| Recruited in 2019 3) | Total recruited  incl. previous years | Recruited in 2019 | Total recruited  incl. previous years |
| !! Details optional !! | | |
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|  | Numerator Indicator No. 7 "Study rate" | |  |  |  |  |

List of studies - liver 1)

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| --- | --- | --- | --- | --- | --- | --- |
| Responsible cooperation partner 2) | | Name of the study | Centre patients | | Patients total | |
| Recruited in 2019 3) | Total recruited  incl. previous years | Recruited in 2019 | Total recruited  incl. previous years |
| !! Details optional !! | | |
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|  | Numerator Indicator No. 7 "Study rate" | |  |  |  |  |

List of studies - esophagus 1)

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| --- | --- | --- | --- | --- | --- | --- |
| Responsible cooperation partner 2) | | Name of the study | Centre patients | | Patients total | |
| Recruited in 2019 3) | Total recruited  incl. previous years | Recruited in 2019 | Total recruited  incl. previous years |
| !! Details optional !! | | |
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|  | Numerator Indicator No. 8 "Study rate" | |  |  |  |  |

1) The list of studies must be processed. It is not possible to refer to the Catalogue of Requirements of the Oncology Centre.

2) Responsible cooperation partners: Study unit/specialty unit running the study (e.g. department for radio-oncology, joint haematology/oncology practice Dr. Smith; … ) Designation cooperation partners identical to details on www.oncomap.de, if listed

3) Only those study patients can be counted who are listed as Centre patients in the Centre and were included in the study in 2017 (no double counting of study patients in more than 1 Centre).

| **1.8** **Nursing care** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks of the Centre |  |
| 1.8.1  - All - | Specialised oncological nurses   * At least 1 specialist oncology nurse must be actively employed on day duty. * Oncological nurses are to be designated by name.   The precondition for recognition as a specialist oncology nurse is  ● specialty training specialist oncology nurse in line with the respective federal state regulations  ● or 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 Colorectal Cancer Centre or Visceral Oncology Centre |  |  |
| 1.8.2  - All - | Responsibilities/Tasks   * Specialised assessment and management of strains, symptoms and side-effects * Individual derivation of interventions from nursing standards * Conduct and evaluation of nursing and therapeutic measures * Establishment of individual patient-based need for counselling * The need for specialised counselling is to be defined already in the nursing concept of the Colorectal Cancer Centre. * Ongoing provision of information to and counselling of patients (and their family members) throughout the entire course of the disease * Conduct, coordination and documentation of structured counselling sessions and instructions to patients and their family members. Depending on the concept these activities may also be carried out by other long-serving specialist nurses with oncological expertise. * Participation in the tumour ~~board~~ conference (optional) * Initiation of and participation in multi-professional case discussions/nursing visits. The objective is to find solutions in complex nursing situations. Criteria for the selection of patients are to be laid down. At least 12 case discussions/nursing visits are to be documented for each year and Centre.   Superordinate activities:   * A nursing concept is to be developed and implemented in which the organ-specific aspects of oncological nursing care are taken into account in the Visceral Oncology Centre. * Drawing up of specialised, in-house standards on the basis of (if possible) evidence-based guidelines (e.g. S3-LL Supportive). * Offer of consultation with/supervision by colleagues * Networking between oncology nurses in a joint quality circle and participation in the quality circle in the Visceral Oncology Centre * Interdisciplinary exchange with all professional groups involved in treatment * Responsibility for implementing the requirements for specialist nurse responsible for carrying out chemotherapy (see Section 6)   Colour legend: Change to the version dated 17 October 2018 |  |  |
| 1.8.3  - All - | On-the-job training  The process of familiarising new members of staff must follow a specified oncological on-the-job training concept. |  |  |
| 1.8.4  - All - | Continuing education  A plan for the continuing education of the nurs-ing staff is to be submitted in which the training measures for the forthcoming year are set out.  At least one specific continuing education course per staff member and year (at least 1 day per year) if the staff member performs tasks relevant to the quality of the centre. |  |  |
| 1.8.5  - Colorectal - | Stomatherapy – Staff  Qualification head of stomatherapy  Qualified representative is to be ensured.  Name of staff member is to be given.  If stomatherapy is administered externally, a cooperation agreement is to be entered into.  Recognised training stomatherapy:   * The following continuing education courses run by the FgSKW (Expert association for stoma, continence and wound) as nursing care experts for stoma, continence and wound encompassing 720 continuing education hours or other comparable continuing education courses. The following protection applies to stomatotherapists who were named in the centers before 01/01/2019:   Length of continuing education at least 400 hours plus practical units (contents like “Curriculum nursing expert stoma, continence, wound” of the FgSKW excluding sections incontinence and wound). |  |  |
| 1.8.6  - Colorectal - | Stomatherapy – Definition of tasks   * Pre-inpatient or pre-operative and post-inpatient instructions, counselling and training of patients and their relatives. * Participation in pre-operative marking (or regulated exchange of experience) * Where appropriate, holding of stoma consulting hours |  |  |
| 1.8.7  - Colorectal - | Stomatherapy – Equipment / infrastructure   * Own premises * Possibilities presentation of demonstration material * Storage opportunities for material for stoma care |  |  |
| 1.8.8  - Colorectal - | Communication with other specialties   * Formalised interprofessional information exchange with surgeons, radio-oncology and oncology |  |  |
| 1.8.9  - Colorectal - | Stomatherapy – documentation of therapy   * Documentation in inpatient patient record (documents of the stoma therapists alone not sufficient) * Stoma pass for patients |  |  |
| 1.8.10  - Colorectal - | Stomatherapy – discharge  Further care after discharge is to be described including provision of information for patients. |  |  |
| 1.8.11  - Colorectal - | Stomatherapy – continuing education/specialty training   * Regular training for nurses in inpatient units and relevant specialty units * Regular continuing education for all other professional groups involved and for patients and their relatives * Active support for the work of the self-help organisations through professional further training schemes * Regular own participation in continuing education courses in professional and extracurricular areas |  |  |

| * 1. **General service areas** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks of the Centre |  |
| 1.9.1  - All - | Pastoral care   * Pastoral care in the Centre is to be ensured * Patients must be given the option of care (need is to be actively identified) |  |  |
| 1.9.2  - All - | Nutritional counselling   * Qualified nutritional counselling (carried out by dietitians / ecotrophologists   or specialist with additional training in nutritional medicine) must be an integral part of the Centre   * Cooperation is to be regulated in a cooperation agreement * Need for nutritional counselling is to be actively identified and carried out for each patient. The process must be documented in the patient records.   Colour legend: Change to the version dated 17 October 2018 |  |  |
| - All - | The metabolic risk (nutritional risk) should be recorded at the latest on inpatient admission for, if possible, all tumour patients using Nutritional Risk Screening (NRS), for instance in line with Kondrup 2003 (measures same as S3-LL).  A subsequent, process-guided nutritional consultation / therapy (e.g. nutrition care process) should be demonstrated accordingly.  Colour legend: Change to the version dated 17 October 2018 |  |  |
| - Stomach -  - Esophagus~~-~~  ~~röhre -~~  ~~new~~ | * The measures implemented in line with the S3 Guidelines are to be documented for all patients ~~with an esophageal carcinoma~~. * Pretherapeutic counselling, if possible with dietician * s / ecotrophologists * after esophagectomy/gastrectomy: documented dietary counselling (e.g. nutrition care process) and, where appropriate, training in using enterostomy tubes before discharge   Colour legend: Change to the version dated 17 October 2018 |  |  |
| - Pancreas –  NEW | * after pancreatectomy: Documented dietary advice (e.g. nutrition care process) and, if necessary, training in dealing with pancreatic enzymes and enterostomy tubes before discharge * after pancreatectomy: training through qualified diabetes counseling   Colour legend: Change to the version dated 17 October 2018 |  |  |

| 2. Organ-specific diagnostics **2.1** **Consulting hours** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks of the Centre |  |
| 2.1.1  - Colorectal - | Special consulting hours colorectal   * Basis for staging? (Participating physician, personal authorisation, institute authorisation, polyclinic authorisation) * At least 1 x week |  |  |
| 2.1.2  - Colorectal - | Waiting times special consulting hours   * < 2 weeks waiting time for a consulting hours appointment * < 60 minute waiting time during consulting hours |  |  |
| 2.1.3  - Colorectal - | Clarification tumour dignity  100% clarification dignity already prior to radical surgical procedure (Reasons for deviations are to be given) |  |  |
| 2.1.4  - Colorectal - | Spread diagnosis  Within one week the following tests must be undertaken:   * Abdominal ultrasound * X-ray (lung) * CEA test   If necessary (again within 1 week)   * Other x-ray examinations * CT/MRI; PET-CT (optional) * Scintigraphy * Urological examination * Gynaecological examination |  |  |
| 2.1.5  - Colorectal - | Qualification rectum diagnosis  Details expertise per treatment unit for:   * Rectal endosonography * Rigid rectoscopy * Chromoendoscopy * Proctology |  |  |
| 2.1.6  - Colorectal - | Stenosis  In the case of a non-passable coloscopic stenosis, a renewed full coloscopy must be undertaken post-operatively for 100% of all patients within 3-6 months.  The unit responsible for performing (monitoring appointments) the coloscopy must be clearly defined. |  |  |
| 2.1.7  - Colorectal - | Prevention / screening for asymptomatic population   * External or in-house programmes for counselling risk groups, lifestyle and nutritional recommendations (information events, information material...) * Activities to increase attendance of coloscopy check-ups and FOBT |  |  |
| 2.1.8  - Colorectal - | Indicators early detection / prevention   * Colorectal patients with positive family medical history * Genetic counselling * Immunohistochemical assay DNA mismatch repair proteins MLH1, MSH2, MSH6 and PMS2 | Data sheet colorectal (Excel template) |  |
| 2.1.9  - Colorectal - | List with co-attending physicians / screening network  An up-do-date internal list with co-attending physicians and members of the screening network is to be kept (differentiated presentation of co-attending physicians/screening). |  |  |
| 2.1.10  - Colorectal - | Genetic counselling  Cooperation with genetic counselling is to be regulated in a cooperation agreement.  Cooperation must be proven by way of documented cases during the current assessment period.  The "Centres for Familial Colorectal Cancer" listed by German Cancer Aid (*Deutsche Krebshilfe*) are particularly suited for this. (<http://www.hnpcc.de/>). |  |  |
| 2.1.11  - Colorectal - | Identification and procedure for risk groups (familial and elevated risk)  Risk persons are to be identified and documented in line with the risk classification in the S3 Guidelines when recording their medical history on admission. They have the following characteristics in particular:   * age < 50 years * prior colorectal carcinoma or endometrial carcinoma * one or more colorectal carcinomas in close family members * Endometrial urothelial, small intestine or gastric carcinoma in close family members |  |  |
| - Colorectal - | The algorithms for the genetic diagnostic procedure and molecular-pathological clarification in the case of suspected HNPCC and medical history sheets for the identification of risk persons to clarify the familial and hereditary risk and an information letter about elevated risk of disease onset and recommended early detection tests for close family members can be downloaded on <http://www.krebsgesellschaft.de/deutsche-krebsgesellschaft-wtrl/deutsche-krebsgesellschaft/zertifizierung/erhebungsboegen/organkrebszentren.html> in the section colorectal cancer. |  |  |
| 2.1.12  - Colorectal - | Individual care plan   * In the case of identified risk persons individual care planning must be undertaken in line with the S3 Guidelines.   Procedure in the event of suspected Lnych syndrome  In the SOP for confirming/ruling out Lynch syndrome, the following points are to be borne in mind:   * Responsibility for identifying risk persons * Responsibility for organising the primary immunohistochemical MSI examination and further analyses thereafter * Responsibility for MSI testing * Responsibility for passing on information to patients * Responsibility for referral for genetic counselling/testing |  |  |
| - Pancreas - | Spread diagnosis / diagnostic confirmation  Within one week the following tests must be undertaken:   * Abdominal ultrasound * Endosonography upper gastrointestinal tract (Proof of competence: at least 30 endosonographies/examining physician/year) * Endoscopic ultrasound fine needle biopsy in the abdomen (not only pancreas punctures required) (Proof of competence: at least 10/ examining physician/year) * Multidetector CT * MRI with MRCP * Interventional ERCP (Proof of competence: at least 50/examining physician/year) * X-ray (lung) |  |  |
|  | If necessary (again within 1 week):   * Other X-ray examinations * CT/MRI; PET-CT (optional) * Scintigraphy |  |  |
| - Pancreas - | Complications endoscopy  Proportion endoscopy-specific complications   * Bleeding (onset after ERCP), perforation: < 5% * Pancreatitis (onset after ERC) (=documented in the results system, each degree of severity): ≤ 10% | Data sheet pancreas (Excel template) |  |
| - Stomach - | Consulting hours stomach  After appointment during consulting hours the following tests must be guaranteed within 1 week:   * endoscopy * endoscopic biopsy * chromoendoscopy * endosonography upper gastrointestinal tract (≥ 30 endosonographies / examining physician / year) * endoscopic ultrasound fine needle biopsy (proof of competence: ≥ 10/examining physician/year, not restricted to stomach) * Sonography: abdomen, throat * Multidetector CT: thorax, abdomen |  |  |
| - Stomach - | The following topics are to be covered in the consulting hours in particular:   * pre-operative, where appropriate, therapeutic recording of malnutrition with, if appropriate, targeted nutritional therapy which covers the entire diet spectrum * genetic factors in the case of gastric cancer |  |  |
| - Liver - | Conduct of consulting hours  Specialist for internal medicine and gastroenterology  Experience in treating chronic liver disease |  |  |
| - Liver - | After appointment during consulting hours the following tests must be undertaken within one week:   * dynamic, contrast-enhanced ultrasound (CM-US), CT, (CM-CT) and MRI (CM-MRI) * tumour biopsy |  |  |
| - Liver - | LCC staging and evaluation of clinical condition   * In addition to TNM classification, the BCLC classification is to be used for the therapy stratification of the LCC. * Documentation based on the patient's medical record |  |  |
| - Liver - | Aftercare after curative procedure (transplantation, resection, RFA)  In line with S3-LL every 3-6 months over a 2-year period with multi-phase medical imaging (US, CT, MRI) |  |  |
| - Esophagus-  röhre -  new | Consulting hours esophagus  After appointment during consulting hours the following tests must be guaranteed within 1 week:   * esophagogastroduodenoscopy with high-resolution video endoscopy (see 2.2) * bronchoscopy * chromoendoscopy oder computer-aided chromendoscopy * endosonography upper gastrointestinal tract (≥ 30 endosonographies / examining physician / year) * endoscopic ultrasound fine needle biopsy (proof of competence: at least 10 / examining physician / year; not restricted to esophagus * Sonography: abdomen, throat * Multidetector CT: throat, thorax, abdomen * ENT consultation |  |  |

| **2.2**  **Diagnostics** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks of the Centre |  |
| 2.2.1  - Colorectal - | Qualification of diagnosticians performing colonoscopy  Specialists.   * At least 2 specialists (in the field of practice-based physicians 1 specialist with appropriate cover arrangements) * Specialists must be named * Specialist in internal medicine and gastroenterology * Specialist in visceral surgery * Surgeons and internists with a qualification in colonoscopy (grandfathering) or colonoscopy authorisation by the responsible health insurance fund |  |  |
|  | At least 2 specialists (in the practice-based sector 1 specialist with corresponding cross staff provision)   * The names of the specialists are to be given.   Experience examining physician:   * Coloscopies: 200 patients annually * Polypectomies (only loop): 25 patients annually | Listing of names in the table "Experience examining physician colorectal) (at the end of this section) |  |
|  | Authorisation of new examining physicians in the last 3 years at least 200 coloscopies and 50 polypectomies (only loop). |  |  |
|  | Each coloscopy and polypectomy is to performed/supervised by an examining physician who has the above-mentioned experience. |  |  |
| 2.2.2  - Colorectal - | Performance coloscopy   * Signed declared consent * Patient monitoring Pulse oxymetry Documentation using surveillance sheet after examination with sedation * Photo documentation Completeness of the examination (ileocecal valve, cecal pole, terminal ileum) Polyp removal points (before - after) * Aftercare recommendation Timing control coloscopy |  |  |
| 2.2.3  - Colorectal - | Complications   * Reference to possible complications after coloscopy (information material) * Recording / evaluation complication rates |  |  |
|  | * Complication rate therapeutic Coloscopies * Full elective coloscopies | Data sheet colorectal (Excel template) |  |
| 2.2.4  - Colorectal - | Requirements coloscopy   * Full coloscopy with biopsy of each suspected spot including a rectal examination * Comparison with the results of the referrer |  |  |
| 2.2.5  - Colorectal - | Outpatient polyp removal   * Possibilities of stypsis * Recording of complications * Procedure for handing over non-removable polyps in office-based practices to the inpatient departments of the Colorectal Cancer Centre. - Names of contacts - Definition passing on of information |  |  |
| 2.2.6  - Colorectal - | Pathology report for adenoma   * Distinction between low-grade versus high-grade intraepithelial neoplasms * Details of completeness of removal   Pathology report for carcinoma in adenoma   * Scale of in-depth infiltration (sm-/pT category) * Degree of histological differentiation (grading) * Presence or lack of lymph vessel invasion (L classification) * Evaluation of resection margins (R classification) * Low-risk/high-risk classification |  |  |
| 2.2.7  - Colorectal - | Presentation in the tumour conference  Each carcinoma in the adenoma must be presented in the tumour conference. |  |  |
| 2.2.8  - Colorectal - | Communication of results polypectomy  In-person discussion/information about malignant findings (not on the phone) by coloscopy unit or GP |  |  |
| 2.2.9  - Colorectal - | Infrastructure/work environment   * Emergency equipment Available emergency equipment and written action plan for emergencies * Preparation, sterilisation and traceability of instruments Compliance with the RKI recommendation for the preparation and sterilisation of flexible endoscopes (*inter alia* traceable batch documentation of preparation and sterilisation) |  |  |
| - Stomach - | Endoscopic therapy   * Specialist requirement * Expertise for each endoscopic surgeon * Processes and responsibilities |  |  |
| - Liver - | Requirement contrast-enhanced ultrasound  Requirement performance:   * Specialist for internal medicine and gastroenterology * Specialist for radiology   Requirement ultra-sound enhanced ultrasound devices:   * Instrument class DEGUM level II (<http://www.degum.de/fileadmin/dokumente/service/geraeteliste/geraeteliste_legende.html>) |  |  |
| - Liver - | Diagnosis confirmation/intrahepatic spread diagnosis of LCC is done using  3-phase contrast-enhanced medical imaging methods:   * CM-US or * CM-CT or * CM-MRI (preferably, if necessary via cooperation) |  |  |
| - Liver - | Intrahepatic spread diagnosis  Diagnostic report with details of scale and vessel infiltration:   * Number of LCC-suspicious foci (description of up to 5 foci) * Dimensions of individual foci in mm * Vessel infiltration (macroinvasion) | Data sheet liver (Excel template) |  |
| - Liver - | Extrahepatic spread diagnosis   * Performance CM-CT |  |  |
| - Esophagus-  röhre -  new | Primary diagnosis   * Esophagogastroduodenoscopy: using high-resolution video endoscopy incl. HDTV resolution, chromoendoscopy, virtual chromoendoscopy) with * biopsies of all suspect lesions * Particularly in the case of Barrett mucosa: 4-Q-PEs |  |  |

# Experience examining physician colorectal - coloscopies/polypectomies

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| --- | --- | --- | --- | --- |
| Coloscopy unit (practice/clinic department) | Title, name, first name | Centre 1) from … to | Number coloscopies  ≥ 200 patients a year | Number polypectomies (only loop)  ≥ 25 patients a year |
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1) Period normally the previous calendar year (=indicator year); deviations e.g. in staff fluctuation, appointment of examining physicians for less than one year; in the event of unclear fulfilment 1 examining physician can also be listed twice for 2 periods (e.g. previous calendar year and current year up to date of submission CR)

| 3. Radiology | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks of the Centre |  |
| 3.1  - All - | Specialists   * At least 1 radiology specialist * Cover arrangements with the same qualification is to be documented in writing. * Specialists and their cover staff are to be designated by name. |  |  |
| 3.2  - All - | Radiology RTAs:  At least 2 qualified RTAs must be available and their names given. |  |  |
| 3.3  - All - | Procedures available in radiology:   * conventional X-ray * spiral-CT * MRI (field strength at least 1.5 Tesla) |  |  |
| - Colorectal - | In the diagnostic report MRI/thin-layer CT:  Details of distance mesorectal fascia (quality indicator guidelines) | Data sheet colorectal (Excel template) |  |
| 3.4  - All - | Standard operating procedures (SOPs) for radiology  The imaging techniques are to be described and checked once a year to ensure they are up to date. |  |  |
| 3.5  - All - | Diagnosis  The written report of the radiologists must be available to the co-attending physicians at the latest 24 h after the test. |  |  |
| 3.6  - All - | Continuing education/specialty training   * A training plan for medical and nursing staff is to be presented listing the planned training courses for the period of one year. * At least 1 dedicated continuing education/specialty training course for each staff member (at least 1 day a year) who carries out quality-relevant activities for the Centre. |  |  |
| - Pancreas / stomach /  Esophagus | Availability/On-call  Presence of a radiology specialist during working hours, 24-hour on-call service outside working hours, if necessary through cooperation (including weekends and public holidays) |  |  |
| - Liver - | Interventional radiology  Specialists  At least 1 radiology specialist  with proof of competence of DeGIR/DGNR (German Society for Interventional Radiology/German Society for Neuroradiology) level 2 certificate |  |  |
| - Liver - | Interventional radiology must be available and reachable at the Centre's clinical site 24/7. |  |  |
| - Liver - | The following procedures, along with the SOPS and the names of the responsible persons, must be available:   * TACE/TAE (60 visceral- vascular interventions in the last 3 years/interventionist in malignomas) * Percutaneous ablations (20 percutaneous liver ablations in the last 3 years/interventional oncologist |  |  |
| - Liver - | Percutaneous ablation   * Specialist for internal medicine and gastroenterology * Specialist for radiology   Implementation:   * SOP with names of responsible persons is to be documented * Pretherapeutic embolisation in line with the requirements of S3-LL LCC. * Post-interventional follow-up using CM-US, CM-CT or CM-MRI mandatory |  |  |
| - Liver - | Frequency of bleeding requiring mandatory intervention after percutaneous RFA (e.g. intensive stay, administration of coagulation factors) | Data sheet liver (Excel template) |  |
| - Liver - | Transarterial chemoembolisation (TACE)   * SOP with names of responsible persons is to be documented * Post-interventional follow-up within 4-12 weeks using CM-CT/-MRI * Evaluation of response using RECIST- or modified RECIST- or/ and EASL classification | Data sheet liver (Excel template) |  |
| - Esophagus- | Reachability/on-call and handling complications   * Presence of a radiology specialist with proof of competence DeGIR/DGNR level 1 certificate during working hours, a representative with the same qualifications, if necessary in cooperation, must be ensured. * 24-hour on-call service outside working hours of a radiology specialist (including weekends and public holidays) * The option of CT-guided drainage must be available 24/7. |  |  |

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| 4. Nuclear medicine | | | |
| Section | Requirements | Explanatory remarks of the Centre |  |
|  | The Catalogues of Requirements of the Organ Cancer Centres and Oncology Centres have a uniform table of contents.  For the Visceral Oncology Centres this section does not specify any Technical and Medical Requirements. |  |  |

| 5. Surgical oncology **5.1** **Cross-organ surgical oncology** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks of the Centre |  |
|  | The Catalogues of Requirements of the Organ Cancer Centres and Oncology Centres have a uniform table of contents.  For the Visceral Oncology Centres this section does not specify any Technical and Medical Requirements. |  |  |

| **5.2** **Organ-specific surgical therapy** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks of the Centre |  |
| 5.2.1  - All - | D. Inpatient care  Designation of the wards (centralisation should be the goal when there are several wards) |  |  |
| 5.2.2  - All - | Post-operative care  Care in the following areas is to be laid down in a standard operating procedure (SOP):   * Intensive care (incl. e.g. artificial respiration, tracheotomy etc.) * Physiotherapy * Post-operative pain management * Return to normal food intake |  |  |
| 5.2.3  - All - | Surgical capacity  At least 1 operating theatre must be regularly available for surgical procedures. |  |  |
| 5.2.4 | Surgical expertise Centre |  |  |
| - Colorectal - | Surgical expertise colorectal   * 30 surgical primary cases colon * 20 surgical primary cases rectum | Data sheet colorectal (Excel template) |  |
| - Pancreas - | Surgical expertise pancreas | Data sheet pancreas (Excel template) |  |
| * At least 20 pancreatic resections/year |
| * At least 12 surgical primary cases pancreatic cancer/year |
| Definitions   * Primary casescounted: adenocarcinomas, neuroendocrine carcinomas; not counted IPMNs (intraductal papillary mucinous neoplasms); for full definition see CR 1.2.0 * Surgical primary cases Ony ICD-10 C25 in combination with OPS: 5-524\*, 5-525\* = adenocarcinoma, neuroendocrine carcinoma, **NO** IPMNs * Pancreatic resections Benign + malignant ICDs, also IPMNs; only type of surgical procedure is relevant (=left resection of the pancreas, pancreatic head resection, total pancreatectomy; OPS: 5-524\*, 5-525\*) |  |
| - Stomach - | Surgical expertise stomach (primary cases)   * At least ≥ 20 surgical resections stomach/AEJ (abdominal gastrectomies, sub-total stomach resections and/or transhiatal/abdominothoracic extended gastrectomies in patients with gastric cancer or AEJ)   Definition surgical resection stomach/AEJ:   * ICD-10 C16.01, 16.1-16.9, OPS: 5-425\*, 5-426\*, 5-435\* to 5-438\*   If the centre is not certified as an esophageal cancer centre at the same time, resections according to ICD-10 C15.2 and 15.5 and 16.022 can be included (see also Chapter 1.2.0).  1 Tumours, whose centre is > 2 cm from the esophagogastric junction, are classified as gastric carcinomas even if the esophagogastric junction is affected.  2 Tumors that involve the esophagogastral junction and their center within the prox. 2 cm of the esophagogastral junction (proportion Siewert type I / Siewert type II) is counted as esophageal carcinoma.  Colour legend: change compared to version of 17 October 2018  Colour legend: change compared to version of 20 September 2019 | Data sheet stomach (Excel template) |  |
| - Liver - | Surgical expertise   * 25 surgical interventions in malignant tumours of the liver (resections/transplantations)/Centre/year * Definition resection/transplantation: 5-502\*, 5-504\* | Data sheet liver (Excel template) |  |
| - Esophagus- | Surgical expertise esophagus   * At least 20 complex surgical procedures on the esophagus/year (not restricted to C15/C16.02, incl. benign diagnoses) * Definition complex surgical procedures: OPS: 5-423\*, 5-424\*, 5-425\*, 5-426\*, 5-438.0 and 1 and x   2 Tumours that affect the esophagogastric junction and whose centre is within the prox. 2 cm of the esophagogastric junction (proportion Siewert type I/Siewert type ll), are counted as esophageal carcinomas. |  |  |
| 5.2.5 | Surgeons |  |  |
| - All - | * Basic qualification surgeon The basic qualification is specialist for visceral surgery with additional specialty training Special visceral surgery (from Model specialty training ordinance [Muster-WbO] 2003, status 25 June 2010). The specialist for visceral surgery with the focus on visceral surgery in line with the older Model specialty training ordinance is deemed to be equivalent. The specialist for general surgery or the specialist for visceral surgery without specialty training in line with the MWbO 2010 or later is not recognised   Colour legend: change compared to version of 17 October 2018 |  |  |
| - Colorectal - | * or specialist for general surgery with the European qualification EBSQ Coloproctology |  |  |
| - Pancreas /  liver - | * or specialist for general surgery with the European qualification EBSQ Hepato-Pancreatico-Biliary Surgery (HPB) |  |  |
| - All - | * All patients of the Centre must be operated on directly by one of these surgeons or under his/her supervision (second surgeon). |  |  |
| - All - | * Assistant Recognition as assistant only possible if this is done as part of training (no parallel recognition of cases with 2 surgeons). |  |  |
| - Colorectal - | Colorectal surgeons   * The names of at least 2 colorectal surgeons are to be given.   Expertise for each colorectal surgeon (primary cases)  15 colon carcinomas a year  10 rectal carcinomas a year | Names listed in the table "Colorectal surgeons" (at the end of this section) |  |
|  | Authorisation of new colorectal surgeons in the previous 3 years cumulative at least 20 rectal and at least 30 colon carcinomas as leading surgeon (proof of competence based on surgical reports).  Colour legend: change compared to version of 17 October 2018 |  |  |
| - Colorectal - | Senior colorectal surgeon (optional/alternative)   * Maximum 1 senior colorectal surgeon for each Centre (not clinical site) * Application for qualification evaluation is to be submitted to OnkoZert. * Appointment made under the responsibility of the Centre (precondition - positive qualification evaluation by OnkoZert) * Annual rotation possible |  |  |
|  | Expertise senior colorectal surgeon (primary cases)   * On appointment 45 colon carcinomas and 30 rectal carcinomas in the previous 5 years * On extension Valid qualification certificate 5 years; requirement for extension 45 colon carcinomas and 30 rectal carcinomas in the previous 5 years |  |  |
| - Pancreas - | Pancreas surgeon   * The names of at least 2 pancreas surgeons are to be given (pancreas surgeon can also be colorectal surgeon)     Expertise of each pancreas surgeon   * 10 pancreatic resections a year | Names given in the table "Pancreas surgeons" (at the end of this section) |  |
|  | Authorisation of new pancreas surgeons   * In the previous 3 years cumulative at least 20 pancreatic resections as leading surgeon   Colour legend: change compared to version of 17 October 2018 |  |  |
| - Stomach - | Gastric surgeon   * The names of at least 2 gastric surgeons are to be given (gastric surgeon can also be colorectal/pancreas surgeon).     Expertise for each gastric surgeon   * ≥ 10 surgical resections for gastric carcinoma/AEJ a year   Authorisation of new gastric surgeons   * In the previous 3 years cumulative at least 15 surgical procedures for gastric carcinoma as leading surgeon   Colour legend: change compared to version of 17 October 2018 |  |  |
| - Liver - | Liver surgeon   * The names of at least 2 liver surgeons are to be given (liver surgeon can also be colorectal/pancreas/gastric surgeon).      * Authorisation of new liver surgeon * In the previous 3 years cumulative at least 20 surgical liver interventions (not just LCC) as leading surgeon: typical liver resections (5-502\*), liver transplantation (5-504\*)   Colour legend: change compared to version of 17 October 2018 |  |  |
| - Esophagus- | Esophagus surgeon   * The names of at least 2 esophagus surgeons are to be given (esophagus surgeon can also be colorectal/pancreas/gastric/liver surgeon. * Expertise for each esophagus surgeon ≥ 10 complex surgical procedures on the esophagus/year (OPS: 5-423\*, 5-424\*, 5-425\*, 5-426\*, 5-438.0 and 1 and x) * Authorisation of new surgeons: In the previous 3 years cumulative at least 10 complex surgical procedures on the esophagus |  |  |
| 5.2.6  - All - | Emergency treatment   * Emergency treatment (e.g. bowel obstruction, bleeding) is to be laid down in a standard operating procedure (SOP). * Shift planning for qualified staff (roster/on call rota) |  |  |
| 5.2.7 | Surgical indicators |  |  |
| - Colorectal - | Indicator definition/presentation (Annex)   * Post-operative morbidity - Revision surgical procedures colon - Revision surgical procedures rectum - Post-operative wound infection - Anastomosis insufficiencies colon  (quality indicator guidelines) - Anastomosis insufficiencies rectum  (quality indicator guidelines) * Post-operative mortality * Local R0 resections colon * Local R0 resections rectum * Quality of TME rectum specimen * Pre-operative marking stoma position (quality indicator guidelines) | Data sheet colorectal (Excel template) |  |
| - Pancreas - | * Revision surgical procedures pancreas ≤ 10% * Post-operative wound infections * Mortality post-operative: ≤ 5% * Local R0 resections pancreas | Data sheet pancreas (Excel template) |  |
| - Stomach - | * Revision surgical procedures stomach: ≤ 10% * Post-operative wound infections * 30d mortality post-operative: ≤ 10% | Data sheet stomach (Excel template) |  |
| - Liver - | * 30d mortality post-operative: ≤ 5% * Local R0 resections: ≥ 80% | Data sheet liver (Excel template) |  |
| - Liver - | Radiofrequency ablations (surgical)   * SOP with names of responsible persons is to be documented * Post-interventional follow-up using CM-US, CM-CT or CM-MRI mandatory |  |  |
| 5.2.8  - Colorectal - | Indicator liver metastases resection   * Primary liver metastases resection (colorectal UICC stage IV) * Secondary liver metastases resection (colorectal UICC stage IV) | Data sheet colorectal (Excel template) |  |
| - Esophagus- | Surgical indicators   * Revision surgical procedures: ≤ 10% * Endoscopic R0 resection * Surgical R0 resection * Anastomosis insufficiency: ≤ 15% * Mortality post-operative: ≤ 10% | Data sheet esophagus (Excel template) |  |
| 5.2.9 | Lymph nodes |  |  |
| - Colorectal - | Surgically removed lymph nodes  The right oncological decision is to operate (*inter alia* at least 12 lymph nodes). Any deviation from this is to be discussed with the pathologist. |  |  |
| - Pancreas - | The right oncological decision is to operate (*inter alia* at least 12 **regional** lymph nodes.) Any deviation from this is to be discussed with the pathologist. |  |  |
| - Stomach - | * The operation should be performed oncologically correctly (including at least 16 regional LNs). If there is any deviation from this, this must be discussed with the pathologist. * D2 lymphadenectomy: ≥ 25 lymph nodes   Colour legend: change compared to version of 17 October 2018 |  |  |
| - Esophagus- | two-field lymphadenectomy: ≥ 20 lymph nodes in patients receiving no neoadjuvant therapy |  |  |
| 5.2.10  - All - | Induction of new staff members  Systematic, documented induction of new staff members is to be ensured, which imparts knowledge about the Oncology Centre's respective field of activity.  This induction must take place within three months of commencement of employment. |  |  |
| 5.2.11  - All - | Information/dialogue with patient:  Adequate information must be provided about diagnosis and therapy planning and a dialogue is to be entered into. This includes *inter alia*:   * Presentation of alternative treatment concepts * Offer of and aid in obtaining second opinions * Discharge consultation as a standard procedure   A general description is to be given of the way in which information is provided and the dialogue organised. This is to be documented for each patient in medical reports and minutes/records. |  |  |
| 05/02/2012  - All - | Continuing education/specialty training   * A training plan for medical and nursing staff is to be presented listing the planned training courses for the period of one year. * Every year at least 1 dedicated continuing education/specialty training session for each staff member (at least 1 day a year) who carries out quality-relevant activities for the Centre. |  |  |
| - Stomach -  - Esophagus- | Endoscopic resection (endoscopic submucosal dissection (ESD/endoscopic mucosal resection (EMR))   * should be offered as an option in the case of gastric carcinoma T1a, N0, M0 as an en bloc resection. * should be performed, in the case of HGIEN or mucosal carcinoma (L0, V0, G1/2, without ulcerations) in the Barrett esophagus as full endoscopic resection * should be performed, in the case of HGIEN or mucosal carcinoma (L0, V0 no ulcerations, G1/2, sm1/m2) in the squamous epithelium as an endoscopic en bloc resection.   For the esophagus module, the option of offering endoscopic therapy is mandatory, for the stomach module it is optional.  For performance the following applies:  Specialist for   * Gastro-enterology * Visceral surgery with additional specialty training Special visceral surgery (Model specialty training ordinance (Muster-WbO) 2003, status 25 June 2010 or specialist for visceral surgery in line with older MWBO) The specialist for general surgery or the specialist for visceral surgery in line with the MWbO 2010 or later is not recognised. |  |  |
| - Stomach –  - Esophagus- | Expertise for each endoscopic surgeon:   * Endoscopic en-bloc resections stomach or endoscopic resection esophagus ≥ 30 resections cumulative total and * 3 endoscopic en bloc resections or endoscopic resections of esophagus/stomach/year   (Proof of competence based on surgical /endoscopy reports as first surgeon or assistant, as trainer; no parallel recognition of cases with 2 surgeons/endoscopic surgeons)   * Inpatient follow-up surveillance after endoscopic en bloc resection * Aftercare after endoscopic en bloc resection for Pt1a, N0, M0 in line with LL |  |  |
| - Stomach - | Indicator: Complications en bloc resection: bleeding, perforation | Data sheet stomach (Excel template) |  |
| - Stomach –  - Esophagus- | The following SOPS are to be described with details of responsibilities:   * Carrying out of stenting * Thermal ablation (not stomach) * Laying of an alimentary fistula * Available emergency equipment and written action plan for emergencies * Preparation, sterilisation and traceability of instruments Compliance with the RKI recommendation for the preparation and sterilisation of flexible endoscopes (*inter alia* traceable batch documentation of preparation and sterilisation) * Availability/On-call * Presence of an endoscopy medical specialist for radiotherapy during working hours, 24-hour on-call service outside working hours, if necessary through cooperation (including weekends and public holidays) including the possibility of stenting |  |  |
| - Esophagus- | Aftercare after endoscopic resection for HGIEN and early carcinoma:   * after endoscopic therapy regular control endoscopies should be performed (after 3 months, then every six months for 2 years and thereafter once a year). * The SOP and the responsible persons are to be described. |  |  |

Table "Colorectal surgeons"

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Title, name, first name | Has basic  qualification 1) yes/no | Senior colorectal surgeon 2) yes/no | Period 3) from … to | Number surgical procedures 4) colon ≥ 15 | Number surgical procedures 4) rectum ≥ 10 | Clinical site/clinic 5) |
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|  |  |  |  |  |  |  |
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|  |  |  |  |  |  |  |

Table "Pancreas surgeons"

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Title, name, first name | Has basic  qualification 1) yes/no | Period 3) from … to | Number surgical procedures pancreas ≥ 10 | Clinical site/clinic 5) |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

Table "Gastric surgeons"

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Title, name, first name | Has basic  qualification 1) yes/no | Period 3) from … to | Number of surgical procedures stomach ≥ 10 | Clinical site/clinic 5) |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

Table "Esophagus surgeon"

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Title, name, first name | Has basic  qualification 1) yes/no | Period 3) from … to | Number of surgical procedures esophagus ≥ 10 | Clinical site/clinic 5) |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

1. Precondition for basic qualification (in line with CR Section 5.2.5): specialist for visceral surgery with additional specialty training visceral surgery (from Model Specialty Training Ordinance 2003, status 25.06.2010). The following are deemed to be equivalent: specialist for visceral surgery or focus visceral surgery in line with older Model Specialty Training Ordinances. The following are likewise deemed to be equivalent: for the organ colon/rectum the specialist for general surgery with the European qualification EBSQ Coloproctology, for the organs pancreas and liver the specialist for general surgery with the European qualification EBSQ Hepato-Pancreatico-Biliary Surgery (HPB). The following qualifications are not recognised: specialist for general surgery or specialist for visceral surgery without specialty training in line with the Model Specialty Training Ordinance 2010 or later.
2. Precondition senior colorectal surgeon (as specified in CR 5.2.5): positive qualification evaluation by OnkoZert and appointment by the Colorectal Cancer Centre (max. 1 senior colorectal surgeon per Centre)
3. Period normally the previous calendar year (=indicator year); deviations e.g. in staff fluctuation, appointment of surgeons for less than one year; in the event of unclear fulfilment 1 surgeon can also be listed twice for 2 periods (e.g. previous calendar year and current year up to date of submission CR)
4. There is no annual expertise requirement for senior colorectal surgeons
5. What is relevant for multi-site Centres or for the case that a surgeon regularly works in several clinical sites/clinics as a surgeon (surgical expertise is to be detailed for each clinical site/clinic)

Colour legend: Change to the version dated 17 October 2018

| 6. Medicinal Oncology / Systemic therapy **6.1** **Medical oncology** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks of the Centre |  |
|  | The Catalogues of Requirements of the Organ Cancer Centres and Oncology Centres have a uniform table of contents.  For the Visceral Oncology Centres this section does not specify any Technical and Medical Requirements. |  |  |

| **6.2**  **Organ-specific systemic therapy** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks of the Centre |  |
| 6.2.1  - All - | Physicians' qualifications  Specialist for internal medicine and haematology and oncology or specialist for internal medicine and gastroenterology or specialist for radiotherapy  The radio-oncologist can perform chemotherapy in conjunction with radio-chemotherapy concepts.  The name of one representative with the above-mentioned qualification is to be given.  The specialists named here must actively carry out the medicinal tumour therapy. The delegation of responsibilities to physicians without the above-mentioned qualification is not possible. |  |  |
| 6.2.2  - All - | Specialist nurse (outpatient/inpatient)  Requirements for a specialist nurse who is responsible for administering chemotherapy:   * at least 1 year's professional experience in oncology * 50 chemotherapy administrations/year are to be documented (In the case of initial certification an estimate can be given, in the following years this must be documented in the audit). * documentation of training in line with the recommendations of the Conference of Oncological Nursing and Paediatric Nursing Care (*Konferenz Onkologischer Kranken- und Kinderkrankenpflege* - KOK) (KOK recommended actions, administration of cytostatics by specialised nurses) * active involvement in the implementation of the requirements to be met by emergency treatment and therapy of comorbidities and secondary diseases * nursing counselling and/or education of patients is to be documented. |  |  |
| 6.2.3  - All - | On call/reachability medical staff   * 24-hour outside normal working hours including weekends and public holidays * During 24-hour reachability access to therapy data must be possible. |  |  |
| 6.2.4  - All - | Case numbers per treatment unit   * Calculation method: completed ~~chemotherapy~~ systemic / cytostatic / targeted therapy per patient (consisting of several cycles or applications, combined therapies count as one therapy). For therapies lasting over a year, the therapy started in the audit year counts. 1 therapy per patient = 1 therapy line per disease per patient. * In the event of a shortfall, expertise cannot be documented via cooperation (must be documented for each individual treatment unit).   At least 200 ~~chemotherapy~~ drug tumour therapy sessions (cytostatic therapies and / or targeted therapeutics and / or AB / immune therapies, no hormone therapies) a year **or**  Colour legend: change compared to version dated 17 October 2018 |  |  |
| - Colorectal - | at least 50 patients with a specific indication (colon/rectum) |  |  |
| - Pancreas - | at least 20 patients with a specific indication (pancreas) |  |  |
| - Stomach - | at least 20 patients with indication gastric cancer/AEJ tumour |  |  |
| - Esophagus- | at least 20 patients with indication esophageal cancer |  |  |
| 6.2.5  - All - | Structural details per treatment unit   * Number of therapy places outpatient * Number of therapy places inpatient |  |  |
| 6.2.6  - All - | Basic diagnosis laboratory  Basic diagnosis including emergency laboratory must be possible 24 h. If laboratory is not staffed 24 h, written rules/agreement for 24 h emergency laboratory are required. |  |  |
| 6.2.7  - All - | Basic diagnosis medical imaging  Cooperation for ultrasound and radiological emergency and routine diagnosis If medical imaging is not staffed 24 h, written rules/agreement for 24 h emergency diagnosis is required. |  |  |
| 6.2.8  - Colorectal - | * Adjuvant chemotherapies colon /UICC stage lll) (Quality indicator guidelines) * Neoadjuvant chemotherapies rectum (UICC stages ll and lll (Quality indicator guidelines) | Data sheet colorectal (Excel template) |  |
| - Pancreas - | * Adjuvant chemotherapy ≥ 50% * Palliative chemotherapy | Data sheet pancreas (Excel template) |  |
| 6.2.9  - All - | Treatment plan/tumour conference minutes   * The therapeutic procedure should be oriented towards the treatment plans or recommendations of the tumour conference. * The treatment plan/tumour conference minutes must be available in the documentation for each patient. * If there are any deviations from the recommended treatment plan, then they are to be presented at the tumour conference. |  |  |
| 6.2.2010  - All - | Systemic therapy regimens   * The drawing up of / changes to existing therapy regimens must be undertaken by means of regulated release. * Prior to release or changes to therapy regimens, the expert opinion of pharmacists can be sought. * The therapy regimens are to be protected from any unauthorised changes. * The therapy regimens are comparable between the outpatient and inpatient units.   Therapy plans   * All systemic therapy must be planned on the basis of a therapy regimen. * The therapy plans are to be checked and released. |  |  |
| 6.2.11  - All - | Cytostatic preparation   * Production is undertaken with due consideration of statutory provisions (*inter alia* Medicinal Products Act (AMG), GMP, GCP, Eudralex (Volume 10) in a pharmacy. If it is not part of the facility, a care agreement must be entered into. * It must be possible to speak to the pharmacy during the period in which therapy is administered. 24-hour on-call service is required for inpatients. * Standard operating procedures (SOPs) are to be drawn up for production. |  |  |
| 6.2.12  - All - | Standard operating procedures (SOPs)   * The SOP for medicinal oncological therapy is to be described for all phases (start, conduct and conclusion of therapy). * Supportive measures in accordance with the guidelines are to be described for the individual therapy concepts and documented in detail for each patient. |  |  |
| 6.2.13  - All - | Standards comorbidities and secondary diseases  Standards are to be drawn up for the treatment of comorbidities and secondary diseases, in particular for the treatment of paravasates, infections and thromboembolic complications. |  |  |
| 6.2.14  - All - | Emergency treatment  Available emergency equipment and written action plan for emergencies |  |  |
| 6.2.15  - All - | Case-related information/dialogue with patient  Adequate information must be provided about diagnosis and therapy planning and a consultation is to be given. This includes *inter alia*:   * Presentation of alternative treatment concepts * Offer of and aid in obtaining second opinions * Discharge consultation as a standard procedure   Patient consultations are to be documented for each patient in medical reports or in other minutes/records. |  |  |
| 6.2.16  - All - | Information therapy administration/planning  After each administration of systemic therapy, the patient and/or the physician responsible for further treatment are given information about the current therapy status and the next steps (blood test, ...), e.g. via the aftercare pass.  Preparation medical report  After the completion of systemic therapy (last administration) the physician responsible for further treatment or the co-attending physician is given the final report within 7 days. |  |  |
| 6.2.17  - All - | Induction of new staff members  Systematic, documented induction of new staff members is to be ensured, which imparts knowledge about the Oncology Centre's respective field of activity.  This induction must take place within three months of commencement of employment. |  |  |
| 06/02/2018  - All - | Continuing education/specialty training   * A training plan for medical and nursing staff is to be presented listing the planned training courses for the period of one year. * At least 1 dedicated continuing education/specialty training course for each staff member (at least 1 day a year) who carries out quality-relevant activities for the Centre. |  |  |

| **7** **Radio-oncology** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks of the 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.onkozert.de](http://www.onkozert.de/). |  |  |

| **8** **Pathology** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks of the 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.onkozert.de](http://www.onkozert.de/). |  |  |

| **9.** **Palliative care and hospice work** | | | |
| --- | --- | --- | --- |
| Section | Requirements | Explanatory remarks of the Centre |  |
| 9.1  - All - | * Documentation is to be provided of cooperation agreements with service providers offering specialist outpatient and inpatient palliative care and inpatient hospices. Regional care concepts for the integration of palliative care are to be described on the basis of the treatment pathway for patients and family members from the S3 Guidelines Palliative Medicine (Figure 3, p. 174) with the names of all involved persons. * A physician with additional specialty training must be available for consultations and tumour conferences. * The group of patients with incurable cancer is to be defined. They are to be informed in a timely manner about palliative medical support services (SOP). * For patients in a palliative ward symptoms and strains are to be repeatedly recorded using validated tools (e.g. MIDOS, iPOS). * The access to palliative care can be offered in parallel to tumour-specific therapy. The procedure in the Centre is to be described in an SOP. * The number of primary cases with incurable cancer is to be documented. |  |  |
| 9.2  - All - | Supportive therapy and symptom alleviation in the palliative situation   * The options of supportive/palliative inpatient therapy are to be described (SOP/algorithm). * A pain management therapist must be available. The pain management SOP (algorithm) is to be described and confirmed using documented cases for the assessment period. * Access to nutritional counselling is to be described and confirmed using documented cases for the assessment period. * Access to psycho-oncological and psychosocial care and pastoral care is to be described. * If provided by cooperation partners, a cooperation agreement is to be entered into for the above requirements. |  |  |

| **10.** **Tumour documentation/Outcome quality** | | | | | |
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| Section | Requirements | Explanatory remarks of the Centre | | |  |
| 10.1  - All - | Requirements tumour documentation  Tumour documentation, which contains the patient data for a minimum period of 3 months, must be in place at the time of initial certification.  Name of the tumour documentation system in a cancer registry and/or Centre  A data set must be used in line with the Uniform Oncological Basic Data Set and the modules of the Working Group of German Tumour Centres (ADT) and the Association of Population-based Cancer Registries in Germany (GEKID).  The Centre must ensure that data are transferred to the competent cancer registry in a timely manner. Any existing regional laws for notification deadlines are to be complied with. |  | | |  |
| 10.2  - All - | Period covered by the data  The full data are to be presented for the respective last calendar year. |  | | |  |
| 10.3  - All - | Cooperation with cancer register   * Cooperation with the competent 65c cancer registry is to be documented on the basis of the cooperation agreement.[Link Tumorzentren.de](http://www.tumorzentren.de/tl_files/dokumente/Kooperationsvereinbarung%20ADT_DKG_07.07.2015%20.docx) * The OncoBox is to be fed by the competent cancer registry. The full data are to be made available to the cancer register in an ongoing manner. * The presentation of the Catalogue of Requirements and outcome quality should be ensured via the cancer registry to the extent that this information is of relevance for the cancer registry. * As long as the competent cancer registry is unable to meet the requirements imposed, the Centre is to use additional or alternative solutions. The Centre is responsible in the case of a non-functioning external solution. |  | | |  |
| 10.4  - All - | Documentation officer  The name of at least 1 documentation officer is to be given , name/function:  Tasks documentation officer:   * Ensuring and monitoring the timely, full, complete and correct transfer and quality of the patient data that are relevant for certification by all cooperation partners to the cancer registry. * Motivation of trans-sectoral cooperation with participating specialty units in the cancer registry (pathology reports, radiotherapy and medicinal treatments). * Qualification and support for the staff involved in data collection * Regular analysis of evaluations particularly over the course of time. |  | | |  |
| 10.5  - All - | Provision of resources:  The required staff capacity should be made available (for instance 0.5 full-time position for 200 primary cases and 0.1 full-time position for 200 aftercare cases) to perform the documentation tasks and to record data (e.g. by a cancer registry). |  | | |
| 10.6  - Colorectal - - Pancreas - | Selection options  The tumour documentation system must offer the following selection options:   * Cohorts * TNM classification or comparable classifications and prognosis factors * Forms of therapy (surgical therapy, radiotherapy, hormone therapy, immunotherapy, chemotherapy) * Date of recurrence/metastasis * Deaths * Follow-up status (latest update) |  | | |  |
| 10.7  - Colorectal - - Pancreas - | Indicators for outcome quality/scale of aftercare data:  Kaplan-Meier curves:   * Overall survival (OAS) for all patients in subgroups by pT categories, stages * metastasis-free survival for all patients and subgroups * Progression-free survival or disease-free survival for all patients and subgroups * Local recurrence rate for all patients and for subgroups * Survival after progression (PDS) * At the start all cohorts are to be grouped together (3 years). In the case of larger patient numbers and outcome numbers, several cohorts can be evaluated separately. * A table with patient numbers and survival data is a component of each Kaplan-Meier curve. |  | | |  |
| 10.8  - Colorectal - - Pancreas - | Data evaluation   * The depiction of outcome quality (see point above) must be possible for recertifications. * The data in the tumour documentation system are to be evaluated at least once a year in line with the corresponding parameters. * If benchmarking/an annual report is offered, the benchmarking results are to be taken into account in the analysis. * Concrete actions are to be derived from the analysis. * The discussion of results must be done in an interdisciplinary manner and in cooperation with the Centres in the network within the Visceral Oncology Centre. |  | | |  |
| 10.9  - Colorectal - - Pancreas - | Requirements for the follow-up of patients recorded in the matrix Outcome quality |  |  |  |  |
| Minimum requirement for successful recertification |  | ≥ 80 % |  |
| Recertification or maintenance of certification only possible subject to conditions (e.g. reduced validity term, concept for increasing the return rate,...). |  | 60 – 79 % |  |
| Certification was not reconfirmed or maintained. |  | < 60 % |  |

**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 [www.krebsgesellschaft.de](http://www.krebsgesellschaft.de/) and [www.onkozert.de](http://www.onkozert.de/).

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| **Period** | General information for processing the annex   * The actual current values are to be given (no estimates). * Data must normally refer to a calendar year. * Data may be no older than 1 year (data from 2008 are not acceptable for an audit in 2011). * if the "target values" are not achieved for one point, then an explanation is to be given at the corresponding spot in the Catalogue of Requirements | Definition period initial certifications   * At the time of initial certification, the data must be available at least for a period of 3 months (an entire year is ideal); in the case of information on primary cases (CR 5.2.4), surgical procedures per surgeon (CR 5.2.5) and experience of examining physicians (CR 2.2.1), the data for an entire year are always needed * If a full calendar year is not depicted, the period may be more than 4 full months beforehand (based on the certification date). * The selected period must consist of full months (if possible select full quarters) |

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| **Primary case definition**  - Colorectal - |  |  |
| Total primary cases for the Colorectal Cancer Centre are the sum of the types of primary cases given below.   * Malignant diagnosis (adenocarcinoma) must be available * Requirements tumour conference, tumour documentation and aftercare are valid in full.   Types of primary cases   * only endoscopic * surgical * palliative (not surgical) * watch and wait (not surgical curative, not endoscopic) | Primary case definition (only endoscopic)   * No additional surgical tumour removal * Time of counting endoscopic removal   Primary case definition (surgical)   * Malignant first diagnosis rectum (up to 16 cm from an cutaneous line)/colon * Resecting surgical care (stoma installation alone is not sufficient) * Transanal total wall excision * Time of counting = date of surgical tumour removal   Primary case definition palliative (not surgical)   * No surgical tumour removal planned * Time of counting is date of histology report   Primary case definition watch and wait   * Watch and wait patients have newly diagnosed rectal carcinomas which are not initially going to undergo surgical treatment after radiotherapeutic and/or chemotherapeutic pretreatment in the case of full clinical remission. When these patients undergo secondary surgery in the event of tumour recurrence or for other reasons, they count as surgical primary cases. * Time of counting is date of histology report | The following, *inter alia*, are not recognised as surgical primary cases:   * Anal carcinoma (C21) * Palliative bypass surgery * High-grade intraepithelial neoplasms * Palliative stoma installation * Neoadjuvant chemotherapy (tumour has still to be removed surgically) * Port implantation (tumour has still to be removed surgically) * Recurrence * Metastasis surgery |

1. http://www.bmg.bund.de/fileadmin/dateien/Downloads/N/Nationaler\_Krebsplan/Ziel\_5-Nationaler\_Krebsplan.pdf [↑](#footnote-ref-1)