**Catalogue of Requirements for Prostate Cancer Centres**

All of the Requirements for Prostate Cancer Centres are laid down in this Catalogue. The certification of

Prostate Cancer Centres is based on the fulfilment of these requirements.

**Developed by the DKG (German Cancer Society) Certification Commission for Prostate Cancer** **Centres**

**Chairman** Prof. Dr. Martin Burchardt; Prof. Dr. Jan Fichtner

**Members (in alphabetical order):**

ACO Working Group on Surgical Oncology

ADT Working Group German Tumour Centres

AIO Working Group on Internal Oncology

AGORS Working Group Rehabilitation and Social Medicine

AGSMO Working Group in Supportive Measures in Oncology

AOP Working Group on Oncological Pathology

APM Working Group Palliative Medicine

ARO Working Group on Radiological Oncology

ASO Working Group on Social Work in Oncology

AUO Working Group on Urological Oncology

BDP Federal Association of German Pathologists

BDU Professional Association of German Urologists

BNHO Professional Association of Practising Haematologists and Oncologists

BPS Prostate Cancer Self-help Group

BVDST Professional Association of German Radiation Therapists

CAO Working Group Oncology

DeGIR German Society of Interventional Radiology and Minimal-invasive Therapy

DEGRO German Society for Radio-oncology

DGHO German Society for Haematology and Oncology

DGN German Society for Nuclear Medicine

DGP German Society for Palliative Medicine

DGP German Society of Pathology

DGU German Society for Urology

DRG German Radiological Society

DVSG German Association for Social Work in Health Care

dvta German Association of Technical Assistants in Medicine

KOK Conference on Oncological Nursing and Paediatric Nursing Care

OPH Working Group Oncology Pharmacy

PRIO Working Group on Prophylaxis and Integrative Medicine in Oncology

PSO Working Group on Psychological Oncology

Evidence-based Guidelines S3 Prostate Cancer

This **Valid from 31 August 2022**

Catalogue of Requirements (CR) is binding for all audits from 1 January 2023. All changes to the previously

applicable versions of this Catalogue (audit year 2022) are marked in green.

The Catalogue takes account of

* S3-LL Guideline on the early detection, diagnosis and treatment of the different stages of prostate carcinoma

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

**Information on the Prostate Cancer Centre**

|  |  |
| --- | --- |
| Prostate Cancer Centre (PCC) |  |
| Director of the Centre |  |
| Coordinator of the Centre |  |
| Location Name of the clinic |  |
| Place |  |

**QM system certification**

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

**Network/main cooperation partners**

The (main) cooperation partners of Prostate Cancer Centres are registered with the certification agency OnkoZert in a "master data sheet" (*"Stammblatt"*). All the information contained therein is published at [www.oncomap.de](http://www.oncomap.de)/en. The Centre is obliged to report all new and also all invalid cooperations. All other updates (change in management, contact data etc.) must be corrected in the “master data sheet and must be regularly updated before the annual audit/monitoring. This master data sheet can be requested from OnkoZert.

**Preparation/Update**

The electronically generated questionnaire serves as the basis for the PCC's certification. The information provided here has been checked for accuracy and completeness.

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| The data on outcome quality are for the calendar year  |  |

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

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**1.** **General information on the Prostate Cancer Centre**

| **1.1 Network structure**  |
| --- |
| Section | Requirements | Comments by the Prostate Cancer Centre |  |
| 1.1.1 | **Cooperation partners**Main cooperation partners and treatment partners can be part of a clinic or separate practices.Main cooperation partners * Urology
* Radiotherapy
* Internal oncology
* Pathology
* Radiology

Cooperation partners* Psycho-oncology
* Social services
* Nuclear medicine
* Pain therapy
* Self-help group
* Palliative medicine
* Laboratory medicine

Specialties to be brought in amongst others (in Germany according to the German Ordinance on Outpatient Specialist Medical Care (ASV-RL) in this case cooperation agreement is not required, instead for instance standard operating procedure [SOP])* Vascular surgery
* Gastro-enterology
* Cardiology
* Neurology
* Visceral surgery
* Thoracic surgery
* Physiotherapy

Colour legend: Change to version dated 10 September 2021 |  |  |
| **Centre Director**The persons holding the following positions are to be designated by name:* Director(s) of the Centre ((max. 2 directors per Centre, one of whom is the designated contact person)
* Centre Coordinator

Centre Coordinator – tasks* Coordination internal/external audits
* Monitoring of Technical and Medical Requirements and ensuring compliance with them
* Communication interface
* Control/supervision of cross-specialty activities
 |  |  |
| The management structures of the Prostate Cancer Centre, QM responsibilities and network coordination must be clearly defined.* Rules of procedure (regulates relations between the care providers)
* Job description (Quality Manager)
* Job description (Network Coordinator)

This applies in particular to cooperative Prostate Cancer Centres The management of the Prostate Cancer Centre ensures the implementation of standards and legal regulations. |  |  |
|  | **Cooperation models*** A collaboration between up to 2 surgical urological units within a Centre is possible if each surgical urological unit separately documents its surgical primary cases. The number of primary cases must then be at least 200.
* Collaboration between up to 2 surgical radiotherapy units within a Centre is possible if each radiotherapy unit separately documents its expertise.

If a hospital director represents 2 departments, the performance indicators must be calculated separately for each department.Precondition for all cooperation models:* Identical Centre name
* Joint tumour board
* Prior structural evaluation by OnkoZert
 |  |  |
| 1.1.2 | The Prostate Cancer Centre has defined a clear mission statement and quantitative quality targets.Interdisciplinarity and evidence-based medicine are unequivocally reflected in its statements and in its practical work.The Prostate Cancer Centre's fundamental orientation is known to the staff and is being implemented. |  |  |
| 1.1.3 | **Quality target** achievement is measured. The results are subject to documented evaluation.Clear strategies to promote target achievement are defined ~~i~~n an annual quality plan under the responsibility of* the Director(s) of the Centre
* the Coordinator of the Centre
* the Quality Manager

The Quality Manager can also take on the same function in other Organ Cancer Centres. |  |  |
| 1.1.4 | **Cooperation agreements**A cooperation agreement must be signed with cooperating treatment partners. It must be documented that these agreements comply with the Technical and Medical Requirements in the Catalogue of Requirements. The cooperation partners are to be listed in the "master data sheet" (administration by OnkoZert). The agreements are to be examined annually by the Prostate Cancer Centre to ensure they are up to date.The following points are to be regulated: * Binding participation in the pre-therapeutic conference/tumour board
* 24h/7d availability of main clinical cooperation partners in the Centre: urologists, radiologists, haematologist-oncologists
* Description of the treatment processes of relevance for the Prostate Cancer Centre bearing in mind the interfaces
* Obligation to implement indicated Guidelines (S3 Guideline)
* Description of cooperation and interfaces
* Description of cooperation on tumour documentation
* Declaration of willingness to cooperate on internal/external audits
* Commitment to comply with the relevant criteria laid down in the Specialist Requirements for Prostate Cancer Centres (*Fachliche Anforderungen an Prostatakrebszentren* – FAP) and the annual submission of the relevant data
* Declaration of consent of the treatment partner to be publicly identified as part of the Prostate Cancer Centre (e.g. homepage)
* Upholding of confidentiality
* Participation in specialty training programmes and public relations work
 |  |  |
|  |  |  |  |
| 1.1.5 | **Contact persons of the Prostate Cancer Centre:**The contact persons of the Prostate Cancer Centre at the hospital site and for the individual partners must be designated by name and made public (e.g. on the Internet). In medical fields, responsibilities at the specialist level must be defined.Treatment partners that have agreed a form of cooperation with the Centre in writing are referred to as cooperation partners of the Centre. In the absence of such a written agreement, these care providers and treating partners can also care for Centre patients, but they may not refer to themselves as cooperation partners or as part of the certified Centre. |  |  |
|  | **Presentation of the Centre**The overall structure of the Centre is to be presented and made public (e.g. Internet). This also involves providing the names of all internal/external cooperation partners with the following details:* Name, address of cooperation partner

Cooperation partner with tel./email contact details |  |  |
| 1.1.6 | **Strategy planning/reporting**An annual review at management leveI is recommended in which the following aspects, for instance, are examined:* Definition/evaluation and, if appropriate, realignment of goals
* Consideration of audit findings(internal/external)
* Human resources for Centre management(Centre Coordinator)
* Public relations work/Patient information
* Tumour documentation/Outcome quality

The organisation(s) supporting the Prostate Cancer Centre provide sufficient financial and other resources to meet its requirements in terms of HR, premises and supplies/equipment.  |  |  |
| 1.1.7 | **Patient pathways**Overarching patient pathways must be defined in line with the relevant medical guidelines.The patient pathways take into account the Centre's interdisciplinarity and networking with practice-based physicians.Pathways must be laid down for:* Prevention and diagnosis
* Therapy
* Follow-up
* Rehabilitation
* Palliation

Patient pathways can be summarised in a QM manual, for example. |  |  |
| 1.1.8 | **Internal audits**Internal audits must be carried out at least annually and be documented through the submission of audit reports. An internal audit must be conducted for the first time prior to initial certification. |  |  |

| **1.2 Interdisciplinary cooperation**  |
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| Section | Requirements | Comments by the Prostate Cancer Centre |  |
| 1.2.1 | **Number of cases in a Centre**Definition of “Centre case”:* All patients with a primary diagnosis, localised and/or metastatic or recurrence or metastasis, who are presented in the Centre or at the tumour board and receive essential elements of the treatment there (surgery, radiotherapy, systemic therapy, watchful waiting active surveillance, etc.)
* Patients and not stays or surgical procedures
* A patient as a “Centre case” can only be counted for 1 Centre
* Patients, who are only presented for the purposes of seeking a second opinion or for the purposes of consultation, are not counted.
* Interdisciplinary therapy plan must be available
* Time of counting is the (first) presentation in the Centre
* Histology report must be available.
* Complete recording in the tumour documentation system

Definition primary case (subset Centre case):* Patient with initial disease (incl. primary M1)
 |  |  |
| 1.2.2 | Referral of patients with prostate cancer to the Centre:A description must be given of how a patient in the Prostate Cancer Centre can be presented at the pre-therapeutic conference and on what basis a special consultation (with the patient) might be held (SHI-authorised physician, personal authorisation, authorisation by institute or policlinic).Primary referral to main cooperation partner* Referral of the patient to the main cooperation partner at the Centre
* Care provider compiles a therapy plan on the basis of the available findings (biopsy, PSA, therapy suggestion)
* Offer and conduct a patient meeting (if necessary an interdisciplinary meeting)- supplement the therapy plan- if no interdisciplinary meeting desired 🡪 provide surgery date/radiotherapy plan
 |  |  |
| 1.2.3 | Interdisciplinary meeting (optional) Interdisciplinary meetings should be offered for patients of a PCC centre.* Participants: patient + radiotherapist + urologist
* Result: update of the therapy plan

Number interdisciplinary meetings (patients) |  |  |
| 1.2.4a) | **Pre-therapeutic conference*** The pre-therapeutic conference must take place at least once a week at the specialist level for the purpose of therapy planning.
* The responsibilities for preparation, implementation and follow-up must be laid down (see 1.2.6)
* > 95% of the patients hospitalised with the care providers must be presented at the pre-therapeutic conference.
 |  |  |
|  | * Participants: urologist and radiotherapist
* The following are to be presented: All primary cases with no primary M1
 |  |  |
|  | Special features pre-therapeutic conference:* Physical presence of the participants only mandatory in unclear cases. Otherwise, telephone coordination is sufficient. Use of video-conferencing systems is preferable to conference calls.
* Presentation of visual materialPatient-related images (e.g. pathology, radiology) on advanced tumours must be available at the conference, and suitable technical equipment must be provided for the presentation of the visual material. Computer-aided presentation is sufficient.
* If a radiotherapist cooperates with several urological clinics, then this radiotherapy unit must nevertheless present all primary cases who undergo irradiation with a curative intention (see def. Section 7). In addition, the radiotherapy unit must compile a list of all prostate carcinoma patients presented in relation to radiotherapy which classifies the patients according to categories (certified centre, centre with certification in preparation, no centre). A presentation rate of 90% must be reached. The presentation must be documented according to the requirements described here. This patient allocation is also of relevance for tumour documentation.
 |  |  |
| b) | Sequence of the pre-therapeutic conference* The patient is admitted to a care provider of the Prostate Cancer Centre.
* All parameters must be recorded beforehand by the responsible care provider using the "therapy plan" template.
* All cases must be recorded in a list.
* The patient is presented at the conference; parameters are synchronised; the therapy plan is supplemented.
* Physician to whom the patient was primarily presented announces the result within 10 working days via therapy plan to referrer, patient and every physician named by the patient (e.g. copy of the therapy plan).
 |  |  |
| 1.2.5 | **Tumour board:*** The tumour board must be held once a month on the specialist level for the purposes of therapy planning.
* The responsibilities for preparation, conduct and follow-up are to be laid down.
* Participation rate of specialties > 95 %

participants:* Urology
* radiotherapy)
* Haematology/internal oncology
* If the haematologist-oncologist cannot take part in the conference, s/he can be represented by the urologist responsible for chemotherapy (qualification in line with Section 6.2).
* Pathology

Patients to be discussed:* All primary cases with a histology requiring discussion (>pT3a, R1, pN+); generally, no binding obligation for other patients primarily receiving radiotherapy or who underwent curative surgical interventions
* All recurrences or metastatic patients
* At least 10 patients with castration-resistant prostate cancer per year
 |  |  |
|  | Compulsory participation at least every four weeks:* Radiology
* Nuclear medicine

Associated specialist fields (e.g. psycho-oncology, social work, nursing care) and disciplines actively involved in palliative care (neurology, neurosurgery, surgery, pain therapy, orthopaedics, etc.) should be incorporated into the tumour board as required.If several cooperation partners are named for one discipline, the presence of one representative is sufficient if a formalised exchange of information has been set up between them (e.g. via quality circles).Nonetheless, each cooperation partner must attend at least 30% of the tumour boards (four times a year).  |  |  |
| 1.2.6 | **General requirements pre-therapeutic conference/tumour board**The following applies to all pre-therapeutic conferences/tumour boards of the Centre: |  |  |
| a) | **Coordination with referring physicians** Differences or ambiguities compared to the information provided by the referrer must be clarified directly and personally with the referring physician. |  |  |
| b) | **General information on the therapy plan:**The outcome of the pre-therapeutic conference consists, *inter alia*, of a written, interdisciplinary therapy plan ("minutes of the pre-therapeutic conference"/tumour board). It must be part of the patient's records and can simultaneously serve as the medical report.The "minutes of the pre-therapeutic conference" should be automatically generated from the tumour documentation system.The patient can be given a copy of the therapy plan on request. |  |  |
| c) | **Preparation tumour board**The main patient data are to be summed up in writing beforehand and distributed to the participants. A pre-appraisal of suitable study patients is to be undertaken. |  |  |
|  | A written interdisciplinary therapy plan must be compiled for patients who are not presented at the pre-therapeutic conference. |  |  |
| d) | **Presentation of visual material**Patient-related images (e.g. pathology, radiology) – if any exist and are relevant for the issue to be discussed – must be available at the pre-therapeutic conference/tumour board, and suitable technical equipment must be available to present the visual material. Computer-aided presentation is sufficient.Web/online conferenceIf web conferences are held, the sound and the material presented must be transmitted. Care must be taken to ensure that every main cooperation partner is able to present documents and images. |  |  |
| e) | **Minutes**The outcome of the pre-therapeutic conference/tumour board consists, *inter alia*, of a written, interdisciplinary therapy plan ("minutes of the tumour board"). If any deviations from the original therapy plan or from the Guidelines are observed, they must be recorded and evaluated. Depending on the reasons, steps are to be taken to avoid such deviations.It, at the patient’s request, treatment does not start or is discontinued prematurely (despite an existing indication), this must also be recorded.  |  |  |
| f) | **Therapy deviation*** The therapeutic procedure should be oriented towards the therapy plans or recommendations of the pre-therapeutic conference/tumour board.
* If any deviations from the original therapy plan or from the Guidelines are observed, they must be recorded and evaluated. Depending on the cause, avoidance measures are to be taken.
* It shall be demonstrated (e.g. in the form of a concept) how it is ensured that deviations are recorded.

If, at the patient’s request, treatment does not start or is discontinued prematurely (despite an existing indication), this must also be recorded.  |  |  |
| g) | **Participation pre-therapeutic conference/tumour board as continuing education**For the following functions/professional groups, participation in the tumour board is to be made possible:* Assistant staff (MTA, TRA, ...) from the fields of radiology, nuclear medicine and radiotherapy
* Staff members, nurses, social services and psycho-oncology
* Participation in the pre-therapeutic conference/tumour board is recognised as continuing education for the aforementioned functions/professional groups.
 |  |  |
| 1.2.7 | **Metastatic prostate carcinoma**The procedure for diagnosing/treating patients with PSA/metastasis (the patient pathways have to be described – a written procedure for systemic therapy of metastatic prostate carcinoma must be available). |  |  |
| 1.2.8 | **Morbidity/mortality conference** * The participants in the tumour board are the invited participants.
* The conference can be staged on the same date as the pre-therapeutic conference/tumour board.
* A list of participants must be kept.
* M&M conferences are to be held at least twice a year.
* Cases with a special history or a history that could be improved are to be discussed (e.g. grade 3 CTC). All patients who died after surgery/intervention must be discussed.
* Minutes must be taken of the M&M conferences.
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| 1.2.9 | **Quality circle*** The tasks, participants and contents of the quality circles must be laid down.
* At least 4 3 quality circles must be held every year focusing in particular on prostate-specific topics.
* A list of participants must be kept.
* All main cooperation partners participate in the quality circles. Practice-based physicians, for example, can be added to the group of participants. Any main cooperation partners that do not take part in the Centre's quality circles must show that they have held the required number of quality circles themselves (combinations possible).
* Organisation and the taking of minutes are the responsibility of the Centre Coordinator or Quality Manager.
* The quality circles must lead to unequivocal results (actions, decisions) which seem likely to significantly develop/improve the Prostate Cancer Centre.
* A quality circle must have taken place by the time of initial certification. Minutes of the quality circle must have been taken.

Possible topics:* Analysis of outcome quality (benchmarking)
* Interdisciplinary continuing education/specialty training
* Interdisciplinary case reviews
* Structural improvements to the Centre
* Public relations
 |  |  |
| 1.2.10 | **Continuing education/specialty training*** Continuing education/specialty training events are to be offered for the network of the Prostate Cancer Centre at least twice a year (where appropriate also after the MM conferences/quality circles).
* Contents/results and participation are to be recorded. A continuing education/specialty training plan is to be presented.
 |  |  |
| 1.2.11 | **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/specialty training
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| **1.3** **Cooperation with referring physicians and aftercare treatment** |
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| Section | Requirements | Comments by the Prostate Cancer Centre |  |
| 1.3.1 | **Cooperating referrers (integrated care):**A list of cooperating referrers (urologists, general practitioners) must be kept up to date. Referring physicians can present patients to the pre-therapeutic conference/tumour board independently (e.g. suspected recurrence). The referring physicians must be informed about these possibilities.General note:There are, of course, also urologists who are not cooperation partners and for instance only refer patients for diagnosis and therapy. |  |  |
| 1.3.2 | **Referral** of the patient to the PCC Centre:A description has to be given of how a patient in the Prostate Cancer Centre can be presented to the pre-therapeutic conference and on what basis (if necessary) a special consultation (with the patient) might be held (SHI-authorised physician, personal authorisation, authorisation by institute or polyclinic).Reference to Section 1.2.2 CR possible |  |  |
| 1.3.3 | **Providing documents** The urologist or radiotherapist is responsible for drawing up the medical reports for the patients assigned to him/her.≤ 2 working days after the collected documents are ready, the following must be made available to the referring physician, the patient and every physician named by the patient:* Histology
* If appropriate, the minutes of the tumour board/therapy plan
* If applicable, changes to therapy
 |  |  |
| 1.3.4 | **Contact persons** Referring physicians must be provided with relevant information regarding the contact person at the Prostate Cancer Centre (e.g. telephone, e-mail). This can be done by means of the required publication of the cooperation partners. |  |  |
| 1.3.5 | **Feedback system**A written procedure for the co-attending physicians must be in place for collecting, processing and responding to feedback from the referring physician on general and case-specific issues/questions/complications.  |  |  |
| 1.3.6 | **Specialty training** The Prostate Cancer Centre must offer physicians specialty training courses at least twice a year. The contents, results and participants must be recorded. |  |  |
| 1.3.7 | **Referrer satisfaction survey*** Every three years, a referrer satisfaction survey must be conducted. The result of this survey are to be evaluated and analysed. A cross-department survey may be conducted.
* The first satisfaction survey of referring physicians must be completed by the time of the first surveillance audit (1 year after the initial certification).
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| 1.3.8 | **Tumour documentation/follow-up*** Cooperation with the referrers during the follow-up must be described.
* The relevant requirements are described in Section 10 Tumour documentation.
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| **1.4 Psycho-oncology** |
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| Section | Requirements | Comments by the Prostate Cancer Centre |  |
| 1.4.1 | **Psycho-oncology – qualification*** qualified psychologists, qualified to perform a scientifically recognised psychotherapy or
* medical doctors,
* degree/master in social education, qualified to perform a scientifically recognised psychotherapy

In each case with at least 1 additional training in psychotherapy: behavioural therapy, psychodynamic psychotherapy (analytical psychotherapy and depth psychology-based psychotherapy), systemic therapy, neuropsychological therapy (for psychological disorders caused by brain injuries), interpersonal therapy (IPT; for affective disorders and eating disorders), EMDR for the treatment of post-traumatic stress disorders, hypnotherapy for addictions and psychotherapeutic treatment for somatic disorders and specialty training in psycho-oncology (DKG recognized).Licensing: At least 1 person from the network´s psycho-oncological team (inpatient or outpatient) must be licensed (Psychological or medical psychotherapist)Currently recognised qualifications are upheld.Representatives of other psychosocial professions may be admitted if they can provide evidence of the above-mentioned additional qualifications. For this purpose an individual case examination is required. |  |  |
| 1.4.2 | **Psycho-oncology – Availability and access** Every patient must have prompt access in the vicinity to psycho-oncological ~~counselling (must be documented)~~. The threshold to these services must be low.Colour legend: Change to version dated 10 September 2021 |  |  |
| 1.4.3 | **Psycho-oncology resources**Needs-basedat least 1 fully employed psycho-oncologist with the above-mentioned qualifications should be available to the Centre (to be designated by name). |  |  |
| 1.4.4 | **Scope of care provided**~~The number of patients who have received psycho-oncological counselling must be recorded~~ Psycho-oncological care, especially for patients with high distress scores in the distress screening, must be presented.Colour legend: Change to version dated 10 September 2021 |  |  |
|  | Frequency and length of counselling sessions must be recorded. |  |  |
| 1.4.5 | **Premises**A suitable room must be made available for psycho-oncological patient sessions. |  |  |
| 1.4.6 | **Organisation chart**The provision of services is to be regulated in an organisation chart displaying information that includes details of the availability of resources and local presence. |  |  |
| 1.4.7 | **Psycho-oncology – responsibilities** Psycho-oncological care should be offered to patients at all stages of care (diagnosis, inpatient, post-inpatient). Goals and responsibilities of care:* Prevention/treatment of subsequent psycho-social problems
* Activation of personal resources for coming to terms with the situation
* Maintaining quality of life
* Consideration of the social context
* Organisation of subsequent outpatient care through cooperation with providers of outpatient psycho-oncological services
* Public relations work (scheduled events for patients, etc.)

Leading the psychosocial quality circle |  |  |
| Also recommended are:* Offering and coordination of the supervision, continuing education and specialty training for staff
* A discussion twice a year between psycho-oncologists, nursing and medical staff
* Regular written and, if needed, oral feedback to the physician in charge of treatment regarding psycho-oncological activities (e.g. ~~in~~ a consultant’s report or documentation in the medical file).
* Participation in tumour boards as required
* Cooperation with social services and other Centres

Offering and coordination of interdisciplinary intervention offers |  |  |
| Psycho-oncologists should present their work within the Centre at least twice a year. |  |  |
| 1.4.8 | **Documentation and evaluation**In order to identify the need for treatment, screening of the level of mental stress is mandatory (see: ~~S3 Guideline Psycho-Oncology~~ Indicator "Psycho-oncological distress screening) and the result is to be documented. The proportion of patients overburdened in the distress screening has to be shown.~~Psycho-oncological counselling must be continuously documented and evaluated using appropriate instruments.~~Colour legend: Change to version dated 10 September 2021 |  |  |
| 1.4.9 | **Continuing education/specialty training*** At least 1 dedicated continuing education/specialty training course for each employee each year (at least 1 day per year).
* Regular external supervision must be possible (recommended 2x a month).
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| **1.5** **Social work and rehabilitation** |
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| Section | Requirements | Comments by the Prostate Cancer Centre |  |
| 1.5.1 | **Social work - Qualification:*** Social worker/social pedagogue
* Individual case studies according to the guidelines of the professional society are possible
* Additional qualification
* Experience in the medical/oncological field
 |  |  |
| 1.5.2 | **Social services - Resources:**For patient counselling at least one full-time staff member is available in the Centre for 400 counselled patients (not cases) (= primary cases, secondary metastasis, recurrence). The staff resources can be grouped centrally. An organisation chart must be available. |
| 1.5.3 | **Social services** Every patient must have prompt access in the vicinity to social service counselling at all stages of the disease (must be documented). The threshold to these services must be low. |  |  |
| 1.5.4 | **Level of patient care**Scope of the number of patients who receive social service counselling is to be documented and evaluated.  |  |  |
| 1.5.5 | **Premises:**A suitable room must be made available for social service counselling. |  |  |
| 1.5.6 | **Organisation chart:**The provision of these services must be regulated in an organisation chart delineating the availability of resources and local presence.  |  |  |
| 1.5.7 | **Counselling topics:**using the DVSG catalogue of services and the expert standard PEOPSA (Psycho-social Initial Counselling of Oncological Patients by Social Work)* Identification of social, economic and psychological crises
* Initiation of medical rehabilitation measures
* Advice on financial questions and social law (particularly with regard to medical/occupational rehabilitation, disability law, benefits in lieu of pay, retirement benefits etc.)
* Help with applications
* Advice on outpatient and inpatient care options and referring of patients to support and specialist services
* Support with occupational and social reintegration
* Cooperation with social insurance bodies and care providers
* Discharge management

Intervention in crisis situations  |  |  |
| Further tasks:* Offering further education/ information events for other disciplines of the Centre and/or patients
* Public relations and networking
* Participation in multi-professional case reviews, supervision,
* Interdisciplinary cooperation, especially with physicians, nurses, physiotherapists, psycho-oncologists, spiritual counsellors etc.
 |  |  |
| 1.5.8 | **Documentation and evaluation**The activities of social workers must be documented (e.g. CareSD, KIS) and evaluated. |  |  |
| 1.5.9. |

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| **Further /specialty training*** At least 1 specific further /specialty training per employee per year (at least 1 day per year).
* Offering supervision
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| 1.5.10. | **Selection of a rehabilitation facility**Patients should be offered during counselling an oncologic rehabilitation if an indication exists. (see also 1.5.~~6.~~7).Colour legend: Change to version dated 10 September 2021 |  |  |

| **1.6 Patient participation** |
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| Section | Requirements | Comments by the Prostate Cancer Centre |  |
| 1.6.1 | **Patient surveys:*** At least every 3 years over a period of 3 months, all primary-case inpatients (surgical) must have the opportunity to participate in the patient survey.
* The response rate should be higher than 30% (action must be taken if lower).
* The survey can take place during or after the hospital stay.
 |  |  |
| 1.6.2 | **Evaluation of the patient survey:*** Responsibility for the evaluation must be assigned.
* The evaluation must be in relation to the patients of the Prostate Cancer Centre.
* A documented evaluation must take place at least once a year.
* Further action is to be determined on the basis of the evaluation.
 |  |  |
| 1.6.3 | **Patient information (general)*** The Prostate Cancer Centre must present itself and the treatment options comprehensively (e.g. in a brochure, patient folder or on a website).
* The cooperation/treatment partners must be designated by name along with their contact details. The treatment options must be described.
* The options presented must include rehabilitation/aftercare treatment, self-help, treatment measures and alternatives.
 |  |  |
| 1.6.4 | **Discharge consultation** Each patient is given a discharge consultation during which the following topics are mentioned and the corresponding information is provided: e.g. disease status, therapy planning, aftercare, supportive measures (e.g. rehab, medical supplies, psychosocial services). Information available e.g. "Patients' guideline on prostate cancer 1 and 2" (in German) see [www.leitlinienprogramm-oncology.de](http://www.leitlinienprogramm-onkologie.de/) |  |  |
| 1.6.5 | **Patient information (case-related):**The patient should be given the following documents:* The tumour board report/therapy plan
* Medical report/discharge report
* Aftercare plan/aftercare calendar
* Study documentation (if applicable)
 |  |  |
| 1.6.6 | **Programmes for patients**At least once a year the Prostate Cancer Centre must hold scheduled events for patients and/or interested parties.If patient events are (co-)financed by industry, this fact, including potential conflicts of interest of the speakers, must be revealed. The Centre must exclude any direct influence on patients by industry representatives.Colour legend: Change to version dated 10 September 2021 |  |  |
| 1.6.7 | Complaints managementA system of formalised complaints management must be in place. Patients must be given feedback. Complaints are taken into account for the improvement of procedures.  |  |  |
| 1.6.8 | Self-help groupsThe self-help groups with which the Prostate Cancer Centre actively cooperates are to be identified by name. Written agreements must be signed with the self-help groups; they should cover the following:* Access to self-help groups at all stages of therapy (initial diagnosis, inpatient treatment, chemotherapy, …)
* Publication of contact details for the self-help groups (e.g. in patient brochures, website)
* Space for self-help groups to display their brochures
* Regular provision of space at the Prostate Cancer Centre for discussions with patients
* Quality circle with participation of representatives of psycho-oncology, self-help groups, social services, spiritual counselling, nursing and medical staff
* Personal discussions between self-help groups and the Prostate Cancer Centre with the goal of jointly staging and coordinating activities and events. The results of the discussions are to be documented.
* Participation of staff physicians in events staged by self-help groups
 |  |  |

| **1.7 Study management** |
| --- |
| Section | Requirements | Comments by the Prostate Cancer Centre |  |
| 1.7.1 | StudiesAccess to studiesThe patients must have access to studies. The studies conducted at the Prostate Cancer Centre must be compiled in a list and this list should be available to the patients e.g. on the website (incl. a short description of the study) |  |  |
| 1.7.2 | Study leaderThe physician who serves as the study leader must be designated by name. Study assistant/study nurse* A study assistant is to be designated by name for each “unit conducting studies” in the organisation chart for studies.
* The same assistant can act on behalf of a number of “units conducting studies” in parallel.
* Study assistants should be available at the initial certification.
* A certificate on the training course for study assistants should be submitted as documentation of qualifications.
 |  |  |
| 1.7.3 | Study assistant – responsibilitiesThe spectrum of responsibilities must be laid down in writing (e.g. in a job description) and can include the following:* Cooperation with the physician commissioned to conduct the study
* Looking after patients during the study and aftercare
* Organising and coordinating diagnostic and laboratory measures, the investigational medicinal product and the sending of samples
* Collection and documentation of all data relevant to the study
* Preparing and overseeing the audit and inspections by authorities
* The study assistant’s activities can be combined with other activities such as tumour documentation.
 |  |  |
| 1.7.4 | Procedure description:The standard operating procedures (SOPs) for beginning/initiating new studies and for conducting studies (including responsibilities) must be laid down. This comprises for example:* Selecting new studies incl. approval decision
* Internal announcement of new studies (updating study list, etc.)
* Study organisation (special features, supervision, study patients, documentation, etc.)
* How study results are announced (e.g. staff, patients)
 |  |  |
| 1.7.5 | Proportion of study patientsInitial certification: at the time of initial certification ≥ 1 patient must already have been recruited for studies After 1 year: at least 5% of primary casesOnly patients recruited for studies with a positive vote by the ethics committee are counted as study participants. | Enter the value for the indicator under “11. Quality Indicators” |  |
|  | In the event of non-compliance the Centre must meet the following requirements: The Centre must give the reason for non-compliance as well as any steps taken to promote participation in the studies.Only patients recruited for studies with a positive vote by the ethics committee count as participants (non-interventional/diagnostic studies are also recognised, biobank collections are excluded).All study patients can be included when calculating the study rate (proportion of study patients in relation to all primary cases at the Centre).* Patients can be counted once per study; the relevant date is the date of patient consent.
* Patients in palliative and adjuvant situations can be counted, no limitation on stages.

Patients who are recruited for a number of studies in parallel can be counted more than once.  |  |  |
| 1.7.6 | Cooperation with external bodies:If the study is not initiated or implemented (in parts) by the main cooperation partners, this must be clearly regulated via a cooperation agreement. |  |  |

**List of studies**1)

|  |  |  |
| --- | --- | --- |
| Responsiblecooperation partner 2) | Study name | Number of Centre’s patients recruited in 20213) |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  | Numerator: Indicator No. 8 “study rate” |  |

1) The list of studies must be completed. Reference to the Catalogue of Requirements for Oncology Centres is not possible.

2) Responsible cooperation partner: Study unit = department that coordinates the study (e.g. for radio-oncology; haematological/oncological practice-based physician Dr John Smith…). Name of cooperation partner has to be identical with name at [www.oncomap.de](http://www.oncomap.de) if it is listed there.

3) Only those patients who are “Centre patients” and were recruited in 2020 to the study can be counted as “study patients”

 (no double counting of patients in more than 1 Centre).

| **1.8 Nursing Care** |
| --- |
| Section | Requirements | Comments by the Prostate Cancer Centre |  |
| 1.8.1 | **Specialised oncological nurses*** At least one full-time specialist oncology nurse must work on day duty in the Centre. Oncology nurse specialist can be counted for the Uro-oncology Centre.
* The specialist oncology nurses must be designated by name.
* In areas in which patients are treated, the activity of a specialist oncology nurse is to be documented.
* The performance of tasks/cover staff arrangements are to be laid down in writing and documented.

At the time of initial certification, the previous submission of at least one application for training as an “oncological nurse” is required. In this case, it must be explained how the “responsibilities/tasks” described in the following are to be performed during the training period. Cooperation with previously trained oncological nurses, who provide support in performing tasks, is recommended during the training phase. After 3 years, an oncological nurse must be documented. The precondition for recognition as a specialist oncology nurse is: * Continuing education specialist oncology nurse in line with the respective federal state regulations
* or the Model Federal State Ordinance of the German Hospital Federation (*Deutsche Krankenhausgesellschaft e.V.* - DKG)
* or Advanced Practice Nurse (master title) plus 2 years’ practical oncological occupational experience (full-time equivalent)
 |  |  |
| 1.8.2 | **Patient-related tasks:*** Specialist evaluation of symptoms, side-effects and stress/strain
* Individual determination of interventions on the basis of nursing standards
* Conduct and evaluation of nursing and therapeutic measures
* Identification of individual patient-based need for counselling.
* The need for specialist counselling is to be defined already in the nursing concept of the Prostate Cancer Centre
* Ongoing provision of information to and counselling of patients (and their family members) throughout the entire course of the disease and conduct, coordination and documentation of structured counselling sessions and instructions to patients and their family members. In line with the concept these activities may also be carried out by other long-serving specialist nurses with specialist oncological expertise.
* Need-based participation in the tumour board (in line with Chapter 1.2)
* 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

Overarching 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 Prostate Cancer Centre.
* Drawing up of specialist in-house standards based (if possible) on evidence-based guidelines (e.g. S3-LL Supportive)
* Offer of consultation/supervision by colleagues
* Networking between oncology nurses in a joint quality circle and participation in a quality circle in the Prostate Cancer Centre.
* Interdisciplinary exchange with all professional groups involved in treatment
* Responsibility for implementing the requirements for the specialist nurse who administers chemotherapy (see Section 6.2.2)
 |   |  |
| 1.8.3 | **Nursing concept**A nursing concept that takes specific aspects of oncological care into account is to be developed and implemented.  |  |  |
| 1.8.4 | **Induction** The induction of new staff members must be undertaken on the basis of a specialist oncological induction catalogue/plan with the participation of the specialist oncology nurse. |  |  |
| 1.8.5 | **Continuing education**A plan for the continuing education of the nursing staff is to be submitted in which the training measures for the coming year are described.At least one dedicated continuing education measure for each staff member each year (at least 1 day per year) who carries out quality-relevant tasks for the Centre. |  |  |

| * 1. **General service areas**
 |
| --- |
| Section | Requirements | Comments by the Prostate Cancer Centre |  |
| 1.9.1 | **Supportive therapy** * The possibilities for supportive therapy (procedure details/algorithm) at every stage of the therapy have to be described.
* A pain therapist must be designated by name and be available as a fixed contact person for consultations.
* For inpatient care it is necessary to provide information about social work counselling services and access to psycho-oncological care. The responsible person must be designated by name.
* Access to chaplain services has to be described.
* If these services are provided by cooperation partners, a cooperation agreement for the above-mentioned requirements must be concluded.
 |  |  |

**2** **Organ-specific Diagnostics**

| **2.1 Consulting hours** |
| --- |
| Section | Requirements | Comments by the Prostate Cancer Centre |  |
| 2.1.1 | **Number of physicians/specialists** working for the Prostate Cancer Centre in the field of urological diagnostics* At least 1 specialist for urology
* Specialists have to be designated by name
 |  |  |
| 2.1.2 | **Waiting times for special consulting hours**< 2 weeks wait for an appointment< 2 weeks wait for an appointment for ultrasound-directed punch biopsy < 2 weeks Presentation at pre-therapeutic conference or tumour boardIn total, the period for consultation on the treatment recommendation must not exceed 6 weeks.~~of the pre-therapeutic conference with the patient during the consulting hours.~~Colour legend: Change to version dated 10 September 2021 |  |  |
| 2.1.3 | **Waiting times during consulting hours**Requirement: < 60 min Waiting times for an appointmentRequirement: < 4 weeksThe waiting times must be determined by random checks and statistically evaluated (recommendation: an evaluation period of 4 weeks a year). |  |  |
| 2.1.4 | Standard operating procedures (SOPs) for the relevant processes in the field of urological diagnosis must be available. They include *inter alia*:* Diagnosis incl. notification of results (incl. pat. with (local) recurrence and/or remote metastasis)
* Therapy planning (timing pre-operative)
* (Pre-)inpatient admission
* Collaboration with other cooperation partners (mainly external)
* Preparation of patients for the tumour board

Sufficient resources must be available to conduct the SOPs. |  |  |
| 2.1.5 | **Continuing education/specialty training*** A training plan for medical staff (physicians, nurses, technicians, etc.) must be submitted showing the training measures planned for a one-year period:
* Each year at least 1 dedicated continuing education/specialty training course (at least 1 day per year) for each employee who is responsible for quality-relevant work at the Centre.
* If the content required by the 6 training units relevant to prostate carcinoma according to the Oncology Agreement is covered, this content can be credited (in part).
 |  |  |
| 2.1.6  | Equipment description and listing of all ultrasound equipment used in the facility for diagnostic purposes (the possibility of transrectal sonography must be given). |  |  |

| **2.2 Diagnostics** |
| --- |
| Section | Requirements | Comments by the Prostate Cancer Centre |  |
| 2.2.1 | The laboratory should in principle be accredited for the parameters "total PSA" and "free PSA" and be able to submit the appropriate certificate of the German Accreditation Council (DAR). If the laboratory is not accredited, the following conditions/requirements must be met. |  |  |
| 2.2.2 | **Laboratory management:*** Specialist in laboratory medicine
* or clinical chemist
* or specialist in urology with medical knowledge in laboratory medicine
* or Master of Science Biotechnology
* Cover staff arrangements are in place with the corresponding qualifications.
* Consultation with the laboratory management one working days must be possible for the clinicians of the PCC.
* A medical specialist or the laboratory director carries out the medical validation of the laboratory findings.
 |  |  |
| 2.2.3 | **Medical-technical laboratory assistants (MTLAs)*** The analyses are only conducted by qualified MTLAs.
* The MTLAs carry out the technical validation of the measurement results.
 |  |  |
| 2.2.4 | **Parameters:*** Mandatory determination of total PSA (tPSA) within one working day
* Optional determination of free PSA (fPSA) and calculation of the PSA quotient within one working day, or optional determination of complexed PSA (cPSA) within one working day.
* Optional determination of ultra-sensitive PSA
 |  |  |
| 2.2.5 | **Internal quality assurance in the laboratory:*** According to the Guidelines of the German Medical Association.
 |  |  |
| 2.2.6 | **Manufacturers of diagnostic agents and analysis systems:*** No requirements regarding choice of manufacturers of diagnostic agents or the analysis system used
* When there is a change in manufacturer, the comparability of the measurements must be determined based on parallel analyses (old/new system) or analyses of retained samples.
 |  |  |
| 2.2.7 | **Findings:*** Cumulative communication of results must be possible
* Information on the cut-off value
* Information on the PSA quotient
* Information on age-appropriate reference intervals
 |  |  |
| 2.2.8 | * Successful participation in 4 interlaboratory tests per year on total PSA and free PSA (proof).
* Standardised pre-analytics, analytics and post-analytics according to compiled SOPs.
 |  |  |
| 2.2.9 | **Biopsy*** The correct indication for TRUS biopsy of the prostate must be shown.
* At least 20% of the patients with punch biopsies must test positive.
* At least 10 punch biopsy cylinders at least 1 cm in length must be taken.

An evaluation must be submitted. |  |  |

| **3** **Radiology** |
| --- |
| Section | Requirements | Comments by the Prostate Cancer Centre |  |
| 3.1 | **Specialists.*** At least 1 specialist in radiology
* Cover staff arrangements with the same qualifications must be documented in writing.
* The specialists and their cover staff are to be designated by name.
 |  |  |
| 3.2 | **Radiology technicians (MTRAs)** * At least 2 qualified radiology technicians must be available and designated by name.
 |  |  |
| 3.3 | **Radiology methods/devices to be offered*** Conventional X-ray
* Spiral CT for remote metastasis staging
* Ultrasound (including transrectal ultrasound scan)
* (obligatory if possible and available as a health insurance service: multiparametric) MRI for staging, MRI for detection: technical specification in accordance with PI-RADS v2.1(1.5 or 3 Tesla)
 |  |  |
| 3.4 | Imaging for staging and the report on findings must be guaranteed on the same or next working day. |  |  |
| 3.5 | **Quality standards mpMRI**For the performance of mpMRI, the currently valid DRG/BDR quality standards must be taken into account (Franiel T, et al. DOI 10.1055/a-1406-8477). The implementation is to be presented. |  |  |
| 3.6 | **Standard operating procedures for radiology (SOPs)**The imaging SOPs are to be described and checked once a year to ensure they are up to date.  |  |  |
| 3.7 | **Writing findings**The radiologist's written report must be available to the attending physicians no later than 48 hours after the examination.The MRI of the prostate must be appraised in a standardised way, e.g. according to the recommendations of the European Consensus Meeting. |  |  |
| 3.8 | **Continuing education/specialty training*** A training plan for physicians and other staff members (radiological technicians) must be submitted in which the training measures for the coming year are described
* Each year at least 1 dedicated continuing education/specialty training course (lasting > 0.5 day) for each employee who is responsible for quality-relevant work at the Centre.
 |  |  |

| **4** **Nuclear Medicine**  |
| --- |
| Section | Requirements | Comments by the Prostate Cancer Centre |  |
| 4.1 | **Specialists in nuclear medicine:*** At least 1 specialist in nuclear medicine is available
* Cover staff arrangements with the same qualifications must be documented in writing
* Qualified specialists and their cover staff must be designated by name
 |  |  |
| 4.2 | **MTRAs for nuclear medicine:**At least 2 qualified medical-technical radiology assistants (MTRAs) must be available and designated by name. |  |  |
| 4.3 | **Methods:**The imaging methods available in the department have to be describedMandatory:* Bone scintigraphy

Optional:* PSMA-PET- hyprid imaging
* Inpatient radionuclide therapy
 |  |  |
| 4.4 | **Standard operating procedures (SOPs)**The imaging SOPs in nuclear medicine are to be described and checked once a year to ensure they are up to date. |  |  |
| 4.5 | **Preparation of findings**The written findings report must be available to the attending physicians no later than 24 hours after the examination. |  |  |
| 4.6 | **Continuing education/specialty training*** A training plan for physicians and other staff members (radiology assistants) is to be submitted in which the training measures planned for the coming year are described.
* At least 1 unit of prostate-cancer dedicated continuing education/specialty training for each staff member (duration > 0.5 days) who carries out quality-relevant tasks for the Prostate Cancer Centre.
 |  |  |

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| --- |
| **5** **Surgical Oncology** |
| **5.1 Multi-organ surgical therapy** |
|  | The questionnaires of the Organ Cancer Centres and Oncology Centres have a standardised table of contents.This section does not specify any Technical and Medical Requirements for Prostate Cancer Centres. |  |  |

| **5.2 Organ-specific surgical therapy** |
| --- |
| Section | Requirements | Comments by the Prostate Cancer Centre |  |
| 5.2.1 | **Surgical expertise**Number of prostatectomies during uro-oncology surgical procedures per year in the Centre (not relative to primary cases)* 50-74 prostatectomies: If only one surgeon is designated, a second surgeon needs to be designated by the next audit. (see CR Section 5.2.6)
* ≥ 75 prostatectomies => designation of at least two surgeons

Prostatectomies:* Radical prostatectomies (as primary intervention): counts for Data Sheet
* radical cystectomy with bladder cancer AND prostate carcinoma (primary intervention)
* radical cystectomy with prostate carcinoma (primary intervention)
* Radical prostatectomies (treatment of recurrences) - salvage prostatectomy

Information on prostatectomies in basic data(Excel spreadsheet)* For 25-49 prostatectomies: individual case decision. The audit report must contain a recommendation for maintaining the certificate without any constraints (*inter alia* ≥ 100 primary cases).

Designation of surgeons by name  |  |  |
| 5.2.2 | **Bed capacity**must be sufficient for the inpatient care of patients of the Prostate Cancer Centre. Description of:* equipment in the patient rooms
* special features of the department
 |  |  |
| 5.2.3 | **Surgical capacity**At least 1 operating theatre must be regularly available for prostate operations. |  |  |
| 5.2.4 | **Nursing staff capacity**One graduate nurse must always be available per shift in the inpatient surgical unit of the Prostate Cancer Centre. |  |  |
| 5.2.5 | **Post-operative care**Care in the following units is to be laid down in a standard operating procedure (SOP):* Intensive care
* Physiotherapy
* Post-operative pain management
* Possibility of emergency surgical care must be guaranteed 24h/7d.

**Emergency treatment*** Available emergency equipment and written action plan for emergencies
 |  |  |
| 5.2.6 | **Specialists for the Prostate Cancer Centre**At least 2 specialists working for the Prostate Cancer Centre according to the organisation chart (can also be surgeons at the same time). Specialists must be designated by name. |  |  |
| 5.2.7 | **Prostate surgeons**1. Every prostate patient must be operated on by one of the named prostate surgeons (or by a trainee under his/her supervision).
2. First appointment as prostate surgeon: has performed a minimum of 100 radical prostatectomies as first surgeon (extract from the hospital information system or by presenting certificates).
3. Continuation: Each prostate surgeon must prove that s/he performs at least 25 prostatectomies per year or 75 prostatectomies in 5 years. For initial certification this number must be documented in the year before the initial certification (extract from the hospital information system).

AssistanceApproval of assistance only within training (primary cases cannot be counted for both/two surgeons).Name designated prostate surgeonsin chart  |  |  |
| 5.2.8 | **Prostate surgeons**Description of the prostate surgeons' specific qualifications (training) via curricula.* Radical prostatectomy (retropubic, perineal or laparoscopic)
* Nerve-sparing radical prostatectomy
* Removal of the pelvic lymph nodes (including extended-field lymphadenectomy)
* Transurethral palliative therapy of prostate carcinoma (in particular transurethral resection of the prostate)
* Monitoring of complications after surgery
* Metastatic surgery
* At least 1 dedicated prostate training event for each surgeon each year (length > 0.5 day)
 |  |
| 5.2.9 | **Nerve-sparing operation**More than 80% of the patients defined as suitable, who have asked for a nerve-sparing procedure, are given nerve-sparing surgery. The intraoperative assessment by the surgeon must be taken into consideration. |  |
| 5.2.10 | **Information/dialogue with patients:**Sufficient information must be provided on diagnosis and therapy planning, and a dialogue must take place. This encompasses *inter alia*:* Presenting alternative treatment concepts
* Offering and arranging second opinions
* Discharge consultations as a standard procedure.

The type and manner of information provision and dialogue have to be described in general terms. This has to be documented in medical reports and minutes/records for each patient. |  |
| 5.2.11 | The following **quality-relevant SOPS** with details of responsibilities must be described:* Perioperative management
* Discharge management
* Operative management (operation sequences, recycling of material, documentation)
* Post-operative pain therapy
* Emergency care (e.g. bleeding) including shift planning for qualified staff (duty roster/on-call rota).

Sufficient resources must be available to carry out the procedures. |  |
| 5.2.12 | **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 course for each staff member (at least 1 day a year) who carries out quality-relevant activities for the Centre.
 |  |

Prostate surgeons (see CR 5.2.7)

|  |  |  |  |
| --- | --- | --- | --- |
| Name designated prostate surgeons | 2022 |  | Only to be completed if number of prostatectomies < 25 |
|  | 2021 | 2020 | 2019 | 2018 | 5 years2018-2022 |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| Other prostate surgeons(Surgeons in training) |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |
| Total: |  |  |  |  |  |  |  |

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| --- |
| **6.** **Medical/ Internal Oncology** |
| **6.1 Haematology and oncology** |
|  | The questionnaires of the Organ Cancer Centres and Oncology Centres have a standardised table of contents.This section does not specify any Medical and Technical Requirements for Prostate Cancer Centres. |  |  |

| **6.2** **Organ-specific oncologic pharmacotherapy**  |
| --- |
| Section | Requirements | Comments by the Prostate Cancer Centre |  |
| 6.2.1 | **Specialist’s qualifications:**Specialist in internal medicine, haematology and oncology or specialist in radiotherapy or specialist in urologyRequirements for urology specialist* until MWBO (model ordinance on further training) 2018: Further qualification in medical tumour therapy; alternative: participation in the "Oncology Agreement", Annex 7 to the Federal Collective Agreements, regional implementation and
* 5 years’ experience in medical tumour therapy of prostate carcinoma (documentation)

The specialists designated here must actively carry out the drug-based tumour therapy. Responsibility must not be delegated to physicians who do not have the above-mentioned qualification.Colour legend: Change to version dated 10 September 2021 |  |  |
| 6.2.2 | **General requirements*** Cover staff arrangements must be detailed in writing (specialist with the same qualifications).
* The specialists must be designated by name.
 |  |  |
| 6.2.3 | **Specialised nurses**Requirements for the specialised nurse responsible for administering chemotherapy:* Inpatient, day patient or clinical-outpatient units in which medicinal oncological therapy is carried out by non-medical staff must be under the specialist supervision of a specialist oncology nurse. This rule does not apply to cooperating practices.
* At least 1 year of professional experience in oncology
* 50 chemotherapy administrations/year (estimations possible for initial certification, documentation must be provided in the following years)
* Documentation of training according to the recommendations of the KOK (*Handlungsempfehlungen der KOK, Applikation von Zytostatika durch Pflegefachkräfte* (Recommendations of the Conference of Oncological Nursing and Paediatric Nursing Care, administration of cytostatic agents by specialist nurses)
* Active integration in the implementation of requirements for the emergency treatment and therapy of comorbidities and secondary diseases.
* The provision of advice and/or information to the patient by nurses must be documented.
 |  |  |
| 6.2.4 | **On call/availability of medical staff*** 24-hour outside normal working hours including weekends and public holidays
* During 24-hour availability, access to therapy data must be possible.
 |  |  |
| 6.2.5 | **Qualifications of the treatment unit** The executing department must meet the following criteria:1. 20 urological patients with chemotherapy per year (including docetaxel)
2. 5 patients with metastatic, prostate carcinoma per year
3. Case number reflects the expertise of the treatment unit and is not restricted to Centre patients. Instillation or hormone therapies cannot be counted

or1. at least 200 systemic therapies (cytostatic therapies and/or targeted therapeutics and/or antibody/immunotherapies, no hormone therapies) annually (for different types of tumours)
2. incl. 5 patients with metastasised prostate carcinoma and/or kidney urinary bladder carcinoma/year (depending on area of application)

Calculation method: Systemic (= cytostatic therapies and/or targeted therapeutics and/or antibody/immunotherapies) therapy for each patient (consisting of **several** cycles or administrations, combination therapies count as 1 therapy). In the case of cross-year therapies, the therapy commenced in the survey 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 separate treatment unit). |  |  |
| 6.2.6 | **Administration of systemic therapy**Chemotherapy is usually given on an outpatient basis or in a day clinic (also interdisciplinary). Inpatient treatment of complications or palliation is possible (written cooperation).  |  |  |
| 6.2.7 | **SOP descriptions*** All phases of the standard operating procedure (SOP) to be followed for drug-based oncological therapy (beginning, implementation and conclusion of therapy) must be described.
* Supportive measures in line with the Guidelines for the individual therapeutic concepts must be described and documented in detail for each patient.
 |  |  |
| 6.2.8 | **Structural details of each treatment unit*** Number of outpatient therapy places
* Number of inpatient therapy places
 |  |  |
| 6.2.9 | **Basic diagnosis laboratory*** Basic diagnosis including emergency laboratory must be possible 24h/7d.
 |  |  |
| 6.2.10 | **Basic diagnosis medical imaging*** Cooperation for ultrasound and radiological emergency and routine diagnosis (where appropriate through cooperation)
 |  |  |
| 6.2.11 | **Standards for concomitant and secondary diseases**Standards must be drawn up for treating concomitant and secondary diseases, in particular extravasation, infections and thromboembolic complications.  |  |  |
| 6.2.12 | **Emergency treatment**Emergency equipment and a written plan of procedure must be available for emergency situations. |  |  |
| 6.2.13 | Preparation of cytostatics* Production is undertaken with consideration of statutory provisions (*inter alia* Medicinal Products Act (AMG), Ordinance on the Operation of Pharmacies (APBetrO), 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.
 |  |  |
| 6.2.14 | **Palliative care**A written plan exists for palliative therapy. |  |  |
| 6.2.15 | **Information for/dialogue with the patient** Based on the diagnosis and the therapy planning, sufficient information must be conveyed and an appropriate dialogue must be conducted. This includes:* a description of possible treatment options
* offering and arranging a second opinion
* a discharge consultation as a standard procedure

The general way in which information is provided and the dialogue conducted must be described. This is to be documented for each patient in a medical report and in minutes taken/notes.  |  |  |
| 6.2.16 | **Systemic therapy regimens*** The drawing up of /changes to existing therapy regimens must be undertaken by means of regulated approval.
* Prior to approval 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* Each systemic therapy is to be planned on the basis of a therapy regimen. Therapy planning is to be checked and approved.
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| 6.2.17 | **Continuing education/specialty training:*** A plan for the further qualification of physicians, nurses and other staff members is to be submitted in which the training measures for the coming year are described.
* At least 1 dedicated continuing education/specialty training measure every year for each staff member (at least 1 day a year) who carries out quality-relevant tasks for the Prostate Cancer Centre

If the content required by the 6 training units relevant to prostate carcinoma according to the Oncology Agreement is covered, this content can be credited (in part). |  |  |

| **7 Radio-oncology** |
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| Section | Requirements | Comments by the Prostate Cancer Centre |  |
| 7.0 | The Technical and Medical Requirements for radio-oncology are summarised in the “Catalogue of Requirements Radio-oncology” in a cross-organ manner. Irrespective of the number of Organ Cancer Centres/Modules that cooperate with a radiology unit, this “Catalogue of Requirements” is only to be processed once and also only updated once each audit year (objective: no multiple presentations/on-site inspections within one audit year). The “Catalogue of Requirements Radio-oncology” is, therefore, an annex to this Catalogue of Requirements.Download cross-organ “Catalogue of Requirements Radio-oncology” at [www.onkozert.de](http://www.onkozert.de). |  |  |

| **8** **Pathology** |
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| Section | Requirements | Comments by the Prostate Cancer Centre |  |
| 8.0 | The Technical and Medical Requirements for pathology are summarised in the “Catalogue of Requirements Pathology” in a cross-organ manner. Irrespective of the number of Organ Cancer Centres/Modules that work together with a pathology department, this “Catalogue of Requirements” is only to be processed once and also only updated once per audit year (goal: no multiple presentations/on-site inspections within one audit year). The “Catalogue of Requirements Pathology” is, therefore, an annex to this Catalogue of Requirements. Download cross-organ “Catalogue of Requirements Pathology” at [www.onkozert.de](http://www.onkozert.de). |  |  |

| **9 Palliative Care and Hospice Work** |
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| Section | Requirements | Comments by the Prostate Cancer Centre |  |
| 9.1 | * + Cooperation agreements with various providers of specialised inpatient and outpatient palliative care, palliative medical consulting services, inpatient hospices and palliative wards must be documented. Regional concepts (based on the treatment path of the Evidenced-based Guideline: Palliative care for patients with incurable cancer, short version 1.1 – May 2015) for integrating palliative care must be described and the participants designated.
* A physician with additional training in palliative medicine must be available for consultation and, if necessary, for participation in tumour boards.
* The group of patients with incurable cancer has to be informed about palliative care options at an early stage (SOP).
* To identify the need for treatment, it is necessary to carry out a screening to record symptoms and stress (see S3 guideline Palliative Care) (MIDOS or IPOS).
* Access to the palliative care can be offered at the same time as tumour therapy. The procedures in the Centre are to be described in a standard operating procedure (SOP).
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| **10** **Tumour Documentation/Outcome Quality** |
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| Section | Requirements | Comments by the Prostate Cancer Centre |  |
| 10.1 | **Tumour documentation system**A tumour documentation system that contains patient data for a period of at least 3 months must be in place at the time of initial certification. The primary cases of the Centre must be registered in one central tumour documentation system (separate systems for urology/radiotherapy are not permitted).Name of the Centre’s tumour documentation system in the cancer registry and/or Centre. |  |  |
| 10.2 | **Period covered by the data**The data must cover the entire previous calendar year. |  |  |
| 10.3 | **Tumour documentation requirements**A data set must be used in line with the Uniform Basic Oncological Data Set and its modules of the Working Group of German Tumour Centres (ADT) and the Association of Population-based Epidemiological Cancer Registries in Germany (GEKID).The Centre must ensure that data are passed on promptly to the competent cancer registry. Any existing laws for notification deadlines of the federal states (*Länder*) are to be complied with. |  |  |
| 10.4 | **Cooperation with the cancer registry*** Cooperation with the competent 65c cancer registry is to be documented on the basis of the cooperation agreement [Link tumour centres.de](http://www.tumorzentren.de/tl_files/dokumente/Kooperationsvereinbarung%20ADT_DKG_07.07.2015%20.docx)
* The OncoBox should be fed with data from the competent cancer registry. The full data must be transmitted to the cancer registry on an ongoing basis.
* The presentation of the Data Sheet and outcome quality are to be ensured via the cancer registry to the extent that the data concern cancer registration.

Until the competent cancer registry can fulfil these requirements, the Prostate Cancer Centre is to fall back on additional or alternative solutions. The Prostate Cancer Centre bears responsibility for an external solution that is not working.  |  |  |
| 10.5 | **Documentation officer**At least 1 documentation officer must be designated as the person responsible for tumour documentation. Name/function:The documentation officer is responsible for the following tasks: * Ensuring and monitoring the timely, complete and correct transmission and quality of certification-relevant patient data by all cooperation partners to the cancer registry.
* Qualification and support of the staff responsible for data collection

Regular analysis of the evaluations particularly over the course of time |  |  |
| 10.6 | **Provision of resources:**Sufficient resources must be provided for the collection of data and other documentation tasks.Benchmark for the definition of resourcesPer 200 primary cases (a year): 0.5 FTEPer 200 follow-up cases: additional 0.1 FTE |  |  |
| 10.7 | **Selection options**The following selection options must be available in the tumour documentation system: * Year of birth
* TNM classification and prognosis factors
* Types of therapy (surgery, radiotherapy, hormone therapy, immunotherapy, chemotherapy)
* Date of recurrence/metastasis
* Mortalities
* Follow-up status (last update)
 |  |  |
| 10.8 | **Tumour-specific indicators of outcome quality**1. Relapse-free survival by stage (Kaplan-Meier curves) Definition of biochemical recurrence:  a. After radical prostatectomy a PSA level > 0.2 ng/ml confirmed in at least two measurements (2 weeks apart) b. After radiotherapy only, a PSA increase > 0.2 ng/ml above the post-interventional PSA nadir confirmed in at least two measurements (2-3 weeks apart).2. Overall survival by pT categories, stage (Kaplan-Meier curves)3. EPIC-26 incl. additional questionsPatient surveys with EPIC-26 incl. additional questions must be available at the time of the initial certification. |  |  |
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| 10.9 | **Evaluation of data*** Depiction of outcome quality (see above point) must be possible for recertifications.
* Data in the tumour documentation system are to be evaluated at least once a year in line with the corresponding indicators.
* If benchmarking/annual report is proposed, the benchmarking results are to be included in the analysis.
* The results must be discussed in an interdisciplinary manner and within any regional or national networks.
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| 10.10 | **Record of follow-up**A description is to be given of how the follow-up data are collected and what the current follow-up status is (see outcome matrix).Functioning cancer registries show follow-up status.Where this is not an option, joint work is being done on a regional solution together with the centres, the ADT, the DKG and the respective government authoritiesThe follow-up status includes:Any progressions (local recurrences, any regional lymph-node recurrences, remote metastases, at least the first progression)Secondary malignant tumoursDeathsCurrently resides at the addressTermination of follow-up (e.g. patient has moved away from the catchment area, federal state) |  |  |
| 10.11 | Demands on following up the patients covered by the tumour documentation system |  | From 1 Jan. 2013 |  |  |
| Minimum requirement for successful recertification. |  | ≥ 80% |  |
| Recertification or maintenance of certification only subject to certain conditions (e.g. shorter period of validity, concept for raising the response rate, etc.) |  | 60 – 79% |  |
| Recertification or maintenance of certification not issued. |  | < 60% |  |

**Data Sheet/Outcome quality matrix**

A structured EXCEL template is available for Centres to record the indicators and data on outcome quality. This EXCEL Data Sheet also includes the automatic calculation of data quality. Only those indicators presented on the basis of the EXCEL template provided by OnkoZert can be used for certification. No changes may be made to the EXCEL template.

The EXCEL template can be downloaded at [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 figures (no estimates) are to be given.
* Data must normally refer to a calendar year.
* Data must not be more than 1 year old (Data from 2017 are not acceptable for an audit in 2021).
* if the "target values" are not achieved for one item, an explanation must be given in the appropriate section in the Catalogue of Requirements
 | Definition of period for initial certification* At the time of initial certification, data must be available at least for a 3-month period (ideally for an entire year); in the case of information on primary cases/Centre cases (CR1.2.1) and surgical procedures per surgeon (CR 5.2.8), the data for an entire year are always needed
* If a full calendar year is not depicted, the period may not date back more than 4 full months beforehand (based on the certification date).
* The period selected must consist of whole months (if possible select whole quarters)
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