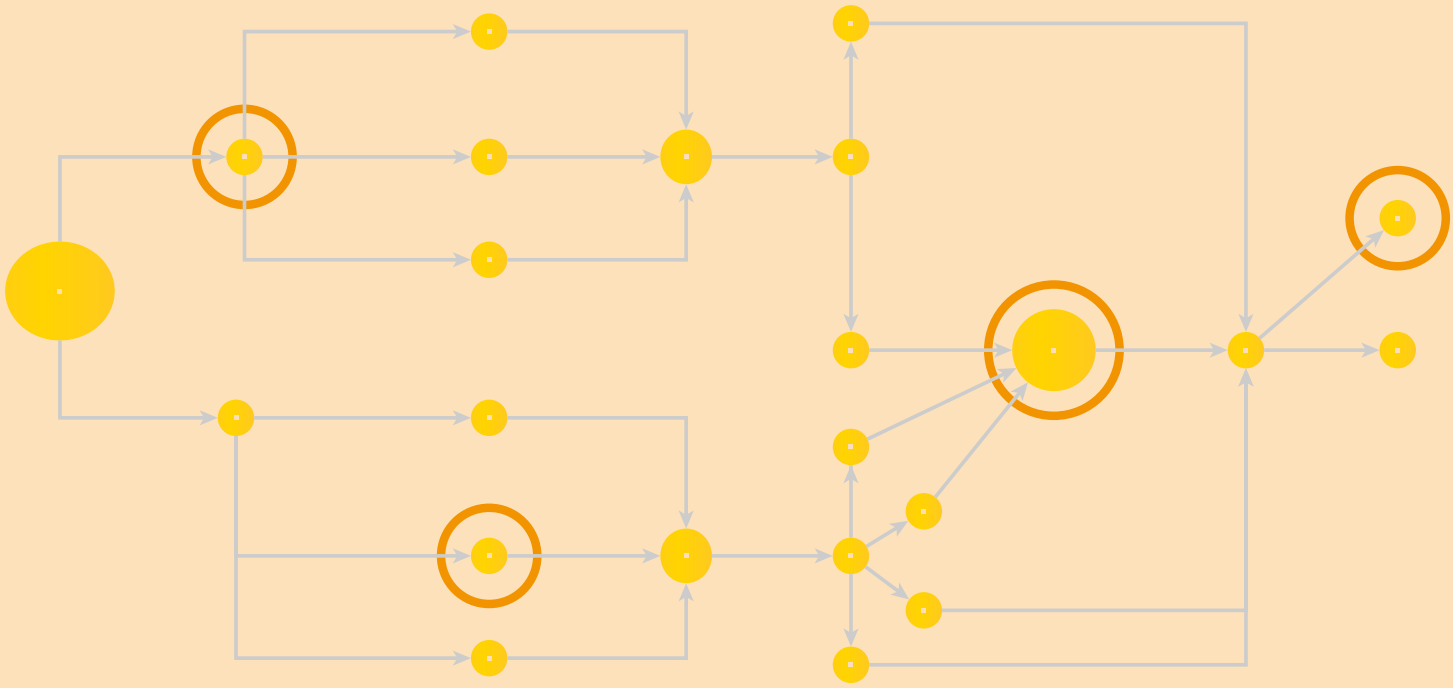
Leitlinienprogramm Onkologie

Oncological quality indicators

Guideline-based quality indicators in the guideline program on oncology (OL)

Version 5.0 February 2021



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Content

1. Foreword

Within the German Guideline Program in Oncology (GGPO) of the Association of the Scientific Medical Societies e.V. (AWMF), the German Cancer Society (DKG) and the German Cancer Aid (DKH), quality indicators are regularly derived for the current guidelines according to a defined process. The methodology for this is described here.

This document is a complete overview of all guideline-based quality indicators defined to date and is updated regularly. The current quality indicators for the GGPO are published in the respective guideline versions at: https://www.leitlinienprogramm-onkologie.de/leitlinien/.

2. Changes compared to German version 4

Indicators on the following topics have been added to the document:

- Anal Cancer
- Follicular lymphoma
- Penile Cancer

Quality indicators were revised for the following topics as part of updates:

- Renal Cell Carcinoma
- Oral cavity carcinoma
- Hepatocellular and biliary carcinomas (consultation)

3. Overview

Guideline topics	Version number, date	Number
Anal Cancer	Version 1.2, December 2020	13
Actinic keratosis and squamous cell carcinoma of the skin	Version 1.1, March 2020	1
Chronic Lymphocytic Leukemia (CLL)	Version 1.0, March 2018	4
Endometrial Cancer	Version 1.0, April 2018	4
Follicular lymphoma	Version 1.0, June 2020	3
Bladder Cancer	Version 2.0, March 2020	12
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Laryngeal Cancer	Version 1.1, November 2019	6
Lung Cancer	Version 1.0, February 2018	8
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Breast Cancer	Version 4.3, February 2020	10
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Palliative care	Version 2.2, September 2020	11
Pancreatic Cancer	Version 1.0, October 2013	5
Penile Cancer	Version 1.0, August 2020	8
Prostate Cancer	Version 5.1, May 2019)	10
Psychooncology	Version 1.1, January 2014	7
supportive therapy	Version 1.3, February 2020	3
Cervical carcinoma - diagnostics, therapy, aftercare	Version 1.0, September 2014	9
Cervical carcinoma - prevention	Version 1.1, March 2020	10
	Total	**221**

4. Anal Cancer

(Version 1.2, December 2020)

Quality indicator	Reference Recommendation	evidence base/ further information
ANAL 1: Pretherapeutic MRI Examination - Pelvis		
Numerator: Patients in the **Denominator** who had a pre-therapeutic MRI scan of the pelvis. **Denominator:** All patients with initial diagnosis of anal carcinoma and therapy	**7.2.** An MRI scan of the pelvis shall be performed to determine the tumor category. [This shall include a multiparametric MRI angulated to the anal canal]. 7.4. MRI of the pelvis shall be performed to detect locoregional lymph node metastases. PET/CT shall be performed in addition. A CT of the pelvis can be performed].	**EC**[1] **Quality objective:** Pretherapeutic MRI examination of the pelvis as often as possible for initial diagnosis of anal carcinoma with therapy.
ANAL 2: Pathological protection of lymph nodes		
Numerator: Patients of the **Denominator** with pathological securing of the lymph nodes **Denominator:** All patients with initial diagnosis of anal carcinoma, cN+ and definitive radiochemotherapy.	**7.5.** In case of imaging suspicion of locoregional lymph node metastasis and planned definitive radiochemotherapy, histopathological or cytopathological confirmation of the suspicious lymph nodes shall not be performed.	**EC** **Quality objective:** No pathological confirmation of lymph nodes in case of imaging suspicion of locoregional lymph node metastasis in case of initial diagnosis of anal carcinoma and definitive radiochemotherapy
Quality Objective: 0%		
ANAL 3: Preoperative examination - anal canal		
Numerator: Patients of the **Denominator** who had a multiparametric MRI angulated to the anal canal or an anal endosonography performed preoperatively **Denominator:** All patients with initial diagnosis of stage I anal carcinoma and resection	**7.8.** Multiparametric MRI angulated to the anal canal or anal endosonography **shall be** performed to determine the presence of sphincter contact prior to performing therapeutic excision for stage I (T1N0M0) anal canal carcinoma or stage I (T1N0M0) or IIA (T2N0M0) anal marginal carcinoma.	**EC** **Quality objective:** As frequent as possible preoperative multiparametric MRI examination angulated to the anal canal or anal endosonography for initial diagnosis of stage I anal carcinoma with resection.

[1] EC: expert consensus

ANAL 4: Pretherapeutic tumor board - stoma creation

Numerator: Patients of the **Denominator** discussed in the pre-therapeutic tumor board. **Denominator:** All patients with initial diagnosis of anal carcinoma and pre-therapeutic creation of a stoma	**8.10.** Patients who require a stoma prior to the start of therapy shall be discussed in the interdisciplinary tumour board.	**EC** **Quality objective:** Presentation of patients with initial diagnosis of anal carcinoma and planned stoma creation in the pre-therapeutic tumour board as frequently as possible.

ANAL 5: Combined radiochemotherapy stage II or III

Numerator: Patients of the **Denominator** with combined radiochemotherapy **Denominator:** All patients with initial diagnosis of anal carcinoma stage II or III	**9.7.** Anal carcinomas of stages II-III **shall be** treated with combined radiochemotherapy.	**A** **GRADE** Low (⊕⊕◯◯) to Moderate (⊕⊕⊕◯). **Quality objective:** Combined radiochemotherapy as often as possible for initial diagnosis of anal carcinoma stage II or III

ANAL 6: Combined radiochemotherapy with mitomycin and 5-FU

Numerator: **Denominator** patients receiving a chemotherapy regimen of mitomycin and 5-FU. **Denominator:** All patients with initial diagnosis of anal carcinoma stage II or III and combined radiochemotherapy	**9.10.** In the context of combined radiochemotherapy, anal carcinomas of stages II-III shall be treated with a chemotherapy regimen consisting of mitomycin and 5-FU.	**A** **GRADE** Moderate (⊕⊕⊕◯) to High (⊕⊕⊕⊕) **Quality objective:** Mitomycin and 5-FU regimen as frequently as possible for initial diagnosis of anal carcinoma stage II or III with combined radiochemotherapy

ANAL 7: Combined radiochemotherapy with IMRT

Numerator: Patients of the **Denominator** who received radiation using intensity-modulated radiotherapy (IMRT). **Denominator:** All patients with initial diagnosis of anal carcinoma stage II or III and combined radiochemotherapy	**9.16.** In the context of combined radiochemotherapy, radiation is **to be** administered by means of intensity-modulated radiotherapy (IMRT).	**A** **GRADE** Very low (⊕◯◯◯) to moderate (⊕⊕⊕◯). **Quality objective:** Intensity-modulated radiotherapy (IMRT) as frequently as possible for initial diagnosis of anal carcinoma stage II or III with combined radiochemotherapy

ANAL 8: Radiochemotherapy and biopsy

Numerator: All patients of the **Denominator** with biopsy after end of radiochemotherapy **Denominator:** All patients with initial diagnosis of anal carcinoma and radiochemotherapy and complete clinical response.	**10.3.** In the case of complete clinical response, no biopsy shall be performed for histopathological confirmation of response.	**EC** **Quality objective:** No biopsy after end of radiochemotherapy in patients with first diagnosis of anal carcinoma and complete clinical response
Quality Objective: 0% **Notes:** Complete clinical response = No residual tumor on clinical examination and MRI 26 weeks after initiation of RCT.		

ANAL 9: Tumor board for residual or recurrent tumor

Numerator: Patients of the **Denominator** with presentation in the tumor board (postoperative or pre-therapeutic) **Denominator:** All patients with initial diagnosis of anal carcinoma and R1/R2 resection or residual tumor after primary radiochemotherapy or patients with recurrent tumor of anal carcinoma.	**12.1.** In the case of residual or recurrent tumour after primary therapy, further treatment planning **shall** take place within the framework of an interdisciplinary tumour board.	**EC** **Quality objective:** As frequent as possible presentation to the tumour board (postoperative or pre-therapeutic) in the case of residual or recurrent tumour after primary therapy in the case of initial diagnosis of anal carcinoma.

ANAL 10: Resection for local recurrence

Numerator: Patients of the **Denominator** with curatively intended resection **Denominator:** All patients with local recurrence of an anal carcinoma, M0 and after primary radiochemotherapy.	**12.2.** In case of residual or recurrent tumor in the area of the primarius (anal/perianal) after primary radiochemotherapy without evidence of distant metastasis, surgical resection shall be performed with curative intent.	**EC** **Quality objective:** Resection for local recurrence of anal carcinoma, M0 and after primary radiochemotherapy as often as possible with curative intent.

ANAL 11: Resection for residual tumor

Numerator: Patients of the **Denominator** with curatively intended resection	**12.2.**	**EC**

Denominator: All patients with residual tumor of an anal carcinoma, M0 and after primary radiochemotherapy.	In case of residual or recurrent tumor in the area of the primarius (anal/perianal) after primary radiochemotherapy without evidence of distant metastasis, surgical resection shall be performed with curative intent.	**Quality objective:** Resection of residual anal carcinoma, M0 and after primary radiochemotherapy as often as possible with curative intent.

ANAL 12: Marking of stoma position

Numerator: Number of patients with preoperative marking of the stoma position **Denominator:** All patients with anal carcinoma who have undergone surgery with stoma creation.	8.11. The stoma position **shall be** marked preoperatively.	**EC** **Quality objective:** Preoperative marking of the stoma position as often as possible in patients with anal carcinoma who have undergone surgery with stoma placement.

ANAL 13: Tumor board in stage IV, M1

Numerator: Patients of the **Denominator** with pre-therapeutic presentation in the tumor board **Denominator:** All patients with anal carcinoma stage IV, M1 (primary or secondary)	**13.1.** In the case of metastatic anal carcinoma in stage IV (distant metastases), further treatment planning **shall** take place within the framework of an interdisciplinary tumour board.	**EC** **Quality objective:** Pretherapeutic presentation of patients with anal carcinoma stage IV, M1 in the tumor board as often as possible
Notes: Participants tumor board: visceral surgery, radiotherapy, oncology, pathology, radiology		

5. Actinic keratosis and squamous cell carcinoma of the skin

(Version 1.1, March 2020)

Quality indicator	Reference Recommendation	Evidence base/ further information
AK/SCC 1: Pathology report*		
Numerator: Number of patients with the following information in the diagnostic report: • histological tumor type, • histological depth extension (description u measurement), • perineural spread, • Vascular intrusion, • Degree of differentiation and • R-classification invasive tumor portion **Denominator:** All patients with SCC and excision	**3.20** The diagnostic report of a SCC shall contain the following in addition to the diagnosis: • histological tumour type (for specific subtypes of SCC) • Description of the histological depth extension in relation to the anatomical stratification (especially from Clark level V, corresponding to infiltration of the subcutis) • Measurement of depth expansion from an invasion depth of 2 mm (corresponds approximately to the diameter of a 10x field of view) • in the case of a positive result, indication of the presence of a perineural proliferation, a vascular herniation or a slight differentiation • Completeness of resection of the invasive tumor portion.	**EC** **Quality Objective:** As often as possible complete information in pathology reports in case of excision of a SCC (squamous cell carcinoma).

*= Indicator can be documented using the basic oncology dataset and associated cancer registry modules (as of 10.2018).

6. Chronic Lymphocytic Leukemia

(Version 1.0, March 2018)

Quality indicator	Reference Recommendation	Evidence base/ further information
CLL 1: Investigation procedures for the initial diagnosis of CLL		
Numerator: Number of patients with total leukocyte count % lymphocytes from Diff-BB immunophenotyping of peripheral blood **Denominator:** All patients with initial diagnosis of CLL	**3.2** Investigation procedures The following examination procedures *shall be used in* the initial diagnosis of CLL: Medical history physical examination with complete survey of peripheral lymph node status and liver and spleen size estimation mechanical blood count (at least haemoglobin, leucocyte count, platelet count) differential microscopic blood count Immunophenotyping of peripheral blood	**Quality Objective:** Determination of total leukocyte count, % lymphocytes from diff. blood and immunophenotyping of peripheral blood for initial diagnosis of CLL as frequently as possible.
CLL 2: Determination of TP53 deletion and mutation status prior to first systemic CLL therapy		
Numerator: Number of patients with determination of TP53 deletion and mutation status (FISH regarding del17p and TP53 mutation analysis ≤ 12 weeks prior to therapy initiation. **Denominator:** All patients with a diagnosis of CLL and first system. Therapy	**3.11** Indication In the case of clinical progression or recurrence with an established indication for therapy, as well as before each start of therapy or a change in therapy, a comprehensive diagnosis shall be carried out promptly. **4** b Test methods The following examination procedures shall be used in the case of clinical progression or relapse with a given therapy indication as well as before each therapy start or a therapy change: Medical history physical examination with complete survey of peripheral lymph node status and liver and spleen size estimation Determination of comorbidity and general health status mechanical blood count differential microscopic blood count	**EC** **Quality Objective:** If possible, frequent determination of TP53 deletion and mutation status (FISH regarding del17p and TP53 mutation analysis ≤ 12 weeks prior to initiation of first systemic therapy.

Quality indicator	Reference Recommendation	Evidence base/ further information
	clinical chemistry Virus serology (CMV, HBV, HCV, HIV, VZV) Determination of TP53 deletion and mutation status (FISH with regard to del(17)(p13) and TP53 mutation analysis) Determination of the current clinical stage	

CLL 3: No chemotherapy alone as first-line therapy in CLL

Numerator: Number of patients with chemotherapy alone **Denominator:** All patients with CLL and first-line therapy	**4.6 Significance of chemoimmunotherapy** Chemoimmunotherapy (taking into account the contraindications for antibody therapies) shall be preferred to chemotherapy alone.	**LoE 4** **Quality Objective:** Chemotherapy alone as first-line therapy for CLL as rarely as possible

CLL 4: Inclusion in clinical trials

Numerator: Number of patients enrolled in clinical trials **Denominator:** All patients with CLL and therapy	**5.1** Recommendation for study participation All patients shall be offered treatment in the context of clinical trials, if available. In particular, when new substances are available, treatment in the context of a clinical trial makes sense for patients with several previous therapies or an unfavourable risk profile.	**EC** **Quality Objective:** Inclusion in clinical trials as often as possible

7. Endometrial Cancer

(Version 1.0, April 2018)

All quality indicators can be compared with the updated uniform basic oncology data set of the Association of German Tumour Centres (ADT) and the Association of Population Based Cancer Registries in Germany (GEKID) (as of 12.02.2014) and the associated modules.

Quality indicator	Reference Recommendation	Evidence base/ further information
Endo 1: No LNE in type I endometrial carcinoma pT1a, G1/2, cN0*.		
Numerator: Number of patients with systematic LNE **Denominator:** All patients with first diagnosis of type I endometrial carcinoma (ICD-0: 8380/3, 8570/3, 8263/3, 8382/3, 8480/3) pT1a, G1/2, cN0	**6.4** In type I endometrial carcinoma (ICD-0: 8380/3, 8570/3, 8263/3, 8382/3, 8480/3) pT1a, G1/2, systematic lymphadenectomy shall not be performed if the lymph nodes are clinically unremarkable.	**LoE 1** **Quality Objective:** No systematic lymphadenectomy for type I endometrial carcinoma pT1a, G1/2, cN0
Endo 2: No adjuvant chemotherapy for type I endometrial carcinoma in stage pT1a/b G1 and G2 cN0/pN0*.		
Numerator: Number of patients with adjuvant chemotherapy **Denominator:** All patients with first diagnosis of type I endometrial carcinoma (ICD-0: 8380/3, 8570/3, 8263/3, 8382/3, 8480/3) pT1a/b G1 cN0/pN0 o. pT1a/b G2 cN0/pN0	**8.2** Patients with endometrioid or other type I endometrial carcinoma (ICD-0: 8380/3, 8570/3, 8263/3, 8382/3, 8480/3) stage pT1a/b G1 and G2 cN0/pN0 shall not receive adjuvant chemotherapy.	**EC** **Quality Objective:** No adjuvant chemotherapy for type I endometrial carcinoma pT1a/b G1 cN0/pN0 o. pT1a/b G2 cN0/pN0

Quality indicator	Reference Recommendation	Evidence base/ further information
Endo 3: Counselling by social services*		
Numerator: Number of patients with advice from social services **Denominator:** All patients with initial diagnosis of endometrial cancer and treatment at the facility.	**11.13** Medical-oncological rehabilitation serves the specific treatment of disease and therapy sequelae. All female patients with EC shall be informed and advised about the legal options for applying for and claiming rehabilitation services.	**EC** **Quality Objective:** Counselling by social services as often as possible
Endo 4: Presentation in the tumor conference*.		
Numerator: Number of patients with presentation at the tumor conference **Denominator:** All patients with endometrial cancer	**12.2** Patients with endometrial carcinoma shall be presented in an interdisciplinary tumor conference.	**EC** **Quality Objective:** Presentation of patients in the tumor conference as often as possible
Note: Tumour conference participants: surgeon, radiologist, pathologist, radiotherapist, internal oncologist, gynaecological oncologist (if system therapy is carried out by gynaecology)		

* Indicator can be documented with the updated uniform basic oncology data set and the associated modules (as of 12.02.2014).

8. Follicular Lymphoma

(Version 1.0, June 2020)

Quality indicator	Reference Recommendation	Evidence base/ further information
FolLymph 1: Confirmation of the diagnosis of follicular lymphoma*		
Numerator: Number of patients with tissue biopsy (tissue biopsy = tissue or bone marrow) **Denominator**: All patients with an initial diagnosis of follicular lymphoma (C82)	4.1. Histological and immunohistochemical examination of a tissue biopsy *shall be* performed to confirm the diagnosis. Strong consensus	**EC** **Quality Objective:** Tissue biopsy as frequently as possible in patients with an initial diagnosis of follicular lymphoma
FolLymph 2: Hepatitis and HIV serology prior to initiation of therapy for follicular lymphoma		
Numerator: Number of patients with hepatitis B, C and HIV serology before systemic therapy **Denominator**: All patients with an initial diagnosis of follicular lymphoma (C82) and systemic therapy.	4.11. Hepatitis B, C and HIV serology shall be performed prior to initiation of systemic therapy.	**EC** **Quality Objective:** Hepatitis and HIV serology as frequently as possible before starting systemic therapy
FolLymph 3: Involved-site or involved-field irradiation for follicular lymphoma		
Numerator: Number of patients with involved-site or involved-field irradiation	6.5. The irradiation shall correspond to an involved-site irradiation.	**EC** **Quality Objective:** As often as possible involved-site or involved-field radiotherapy in first-line therapy Radiotherapy

Quality indicator	Reference Recommendation	Evidence base/ further information
Denominator: All patients with follicular lymphoma (C82) and radiation as first-line therapy		

The **Numerator** is always a subset of the **Denominator**.
* Indicator can be documented with the updated uniform basic oncology data set and the associated modules (as of 06.2019).

9. Bladder Cancer

(Version 2.0, March 2020)

Quality indicator	Reference Recommendation	Evidence base/ further information
BladderCa 1: Contents of findings report		
Numerator: Pat. with report of findings with indication of: • Localization • Number of detected/infested Lk • Capsule overgrowth (y/n) • max. metastasis size (mm, one-dimensional) **Denominator:** All patients with initial diagnosis of bladder carcinoma pN+	**4.16** In the report, the localization (clinical indication), the total number of histologically detected lymph nodes, the number of affected lymph nodes, the maximum metastasis size and capsule-transcending growth shall be mentioned.	**EC** **Quality Objective:** Report of findings with complete information on parameters as often as possible: Localization, number of detected/affected lymph nodes, capsule crossing and max. metastasis size
BladderCa 2: Statement on detrusor musculature in report of findings		
Numerator: Pat. with pathology report stating whether detrusor muscles are included **Denominator:** All patients with bladder carcinoma and TUR-B	**6.15** If no cystectomy is planned, a postresection shall be performed in patients with non-muscle invasive urothelial carcinoma of the urinary bladder with the following constellation: for tumours in which the primary TUR was incomplete if no muscle was detectable in the pathohistological preparation in the initial TUR, except pTa Low Grade for T1 tumours in all high-grade tumours, with the exception of patients with primary carcinoma in situ	**LoE 1-** **Quality Objective:** Statement in the report of findings as to whether detrusor musculature is included as frequently as possible.

Quality indicator	Reference Recommendation	Evidence base/ further information
BladderCa 3: Bilateral pelvic lymphadenectomy during radical cystectomy		
Numerator: Patients with bilateral pelvic lymphadenectomy **Denominator:** All patients with bladder carcinoma and radical cystectomy	**7.22** In the case of invasive bladder carcinoma, a bilateral pelvic lymphadenectomy shall be performed at the same time as the radical cystectomy.	**LoE 2-** **Quality Objective:** If possible, bilateral pelvic lymphadenectomy during radical cystectomy
BladderCa 4: Radical cystectomy within 3 months of diagnosis		
Numerator: Pat. with radical cystectomy within 3Mo after diagnosis **Denominator:** All patients with first diagnosis of bladder cancer >= pT2 and radical cystectomy without neoadjuvant chemotherapy	**7.39** In patients with muscle-invasive bladder cancer who do not receive neoadjuvant therapy, radical cystectomy shall be performed within 3 months of diagnosis if possible.	**LoE 2-** **Quality Objective:** If possible, radical cystectomy within 3 mo of diagnosis without neoadjuvant chemotherapy
BladderCa 5: Simultaneous RCT		
Numerator: Pat. with simultaneous RCT **Denominator:** All patients with bladder carcinoma >=cT2 and curatively intended radiotherapy	**7.45** In the context of a bladder-preserving procedure with curative intention, simultaneous radiochemotherapy shall be performed.	**EC** **Quality Objective:** Simultaneous RCT as often as possible for curatively intended radiotherapy
BladderCa 6: Resection biopsy from the urinary bladder after RT/RCT		
Numerator: Pat. with resection biopsy from the urinary bladder after RT/RCT **Denominator:** All patients with bladder carcinoma and completed RT/RCT	**7.48** As part of the assessment of response, a repeat cystoscopy with sampling from the former resection site shall be performed	**EC** **Quality Objective:** Resection biopsy from the urinary bladder after RT/RCT as often as possible

Quality indicator	Reference Recommendation	Evidence base/ further information
BladderCa 7: Preoperative drawing of stoma position		
Numerator: Pat. with preoperative marking of stoma position **Denominator:** All patients with bladder carcinoma who underwent surgery with stoma creation.	**8.4** A possible stoma position shall be marked preoperatively. The urostomy shall be placed prominently if this is technically possible.	**EC** **Quality Objective:** Preoperative marking of the stoma position as often as possible
BladderCa 8: Pretherapeutic multidisciplinary presentation		
Numerator: Patients with pre-therapeutic multidisciplinary presentation **Denominator:** All patients with initial diagnosis of urinary bladder cancer >= cT2	**9.2** In patients with muscle-invasive bladder carcinoma (≥T2), the therapy concept shall be determined multidisciplinary before the start of therapy.	**EC** **Quality Objective:** Pretherapeutic multidisciplinary presentation as often as possible
Participating disciplines: urologist, internist. Oncologist, Radiotherapist		
BladderCa 9: Postoperative multidisciplinary presentation		
Numerator: Pat. with presentation with postoperative multidisciplinary presentation **Denominator:** All patients with bladder carcinoma >= pT3 u/o pN+	**9.5** In patients with organ-spreading, muscle-invasive bladder carcinoma (≥pT3) and/or pN+, multidisciplinary coordination shall take place for further therapy planning.	**EC** **Quality Objective:** Postoperative multidisciplinary presentation as often as possible
Participating disciplines: urologist, internist. Oncologist, Radiotherapist		

Quality indicator	Reference Recommendation	Evidence base/ further information
BladderCa 10: Counselling by social services		
Numerator: Pat. with counselling by social services **Denominator:** All patients with bladder carcinoma and cystectomy	**10.1** After cystectomy and urinary diversion, patients shall be offered follow-up treatment (AHB). Rehabilitation shall be carried out on an inpatient and specialist urological basis and, if the patient has a corresponding comorbidity, on a multidisciplinary basis and with the aid of multimodal therapy concepts.	**EC** **Quality Objective:** Counselling by the social service after cystectomy as often as possible
BladderCa 11: Consultation with stoma therapist or nursing expert Stoma, continence and wound in case of urostoma		
Numerator: Patients with advice from stoma therapist or nursing expert for stoma, continence and wounds **Denominator:** All patients with bladder cancer and urostoma	**10.7** After the creation of a urostoma, training shall be given in how to care for the stoma independently. Even after the installation of other urinary diversions, the goal is independent care by the patient. Training courses are to be held for this purpose.	**EC** **Quality Objective:** If possible, frequent consultation with stoma therapist or nursing expert Stoma, continence and wound in case of urostoma
BladderCa 12: Risk classification according to EORTC criteria		
Numerator: Patients with risk classification according to EORTC criteria **Denominator:** All patients with NMIBC and TUR	**11.1** After diagnosis of a non-muscle-invasive bladder carcinoma, a risk classification of the tumor (low, intermediate, high-risk) shall be performed according to the risk of recurrence and progression according to the EORTC criteria.	**EC** **Quality Objective:** As often as possible, indication of the risk classification according to EORTC criteria

10. Hepatocellular and biliary carcinoma

(Version 2.01, February 2021)

Quality indicator	Underlying recommendation	Evidence base/ further information
HBC 1: Typing according to WHO classification*		
Numerator: Patients of the **Denominator** with typing according to current WHO classification **Denominator1**: All patients with histologically confirmed HCC **Denominator2**: All patients with histologically confirmed CCA	3.19 The typing of HCC shall be based on the current WHO classification. Special forms (fibrolamellar HCC and mixed tumors (combined HCC/ICC)) and, if possible, early HCC shall be distinguished from progressive HCC and premalignant lesions. A reliable distinction shall be made between special forms of intrahepatic cholangiocarcinoma, liver metastases and also benign liver tumours. 4.8 The typing of carcinomas of the bile ducts and gallbladder shall be done according to the anatomical localization (intrahepatic, perihilar, distal bile ducts, gallbladder) and according to the histological differentiation according to the current WHO classification. For intrahepatic cholangiocarcinomas, a distinction shall be made between 'small duct' and 'large duct' type.	**EC** **Quality objective:** Typing according to WHO as often as possible
HBC 2: Content of findings reports HCC		
Numerator: Patients of the **Denominator** with reports of findings with indication of: • Staging (according to TNM classification) • Typing (according to WHO classification) • Grading • Resection margin • Status of the surrounding liver	**3.20** The processing and reporting of a resectate or explant shall determine the extent of the tumor (staging) according to the current TNM classification, its type (typing) and degree of differentiation (grading), and the status of the resectate margin (R classification) as well as the status of the non-tumorous liver.	**EC** **Quality objective:** Complete diagnostic reports as often as possible

Quality indicator	Underlying recommendation	Evidence base/ further information
Denominator: All patients with HCC and liver resection or liver explantation		

HBC 4: Presentation tumor conference*

Numerator: Patients of the **Denominator** with pre-therapeutic presentation in the tumor conference **Denominator:** All patients with HCC	3.33 Patients with hepatocellular carcinoma shall be presented in an interdisciplinary tumor conference.	**EC** **Quality objective:** Pretherapeutic presentation in the tumor conference as often as possible
Notes: • Participants TK: gastroenterologist, pathologist, interventional radiologist, visceral surgeon • Video conferencing is possible		

HBC 6: Presentation of tumor conference after TACE*

Numerator: Patients of the **Denominator** with presentation at the tumour conference after two treatment cycles **Denominator:** All patients with HCC and TACE	3.66 The indication for continuation of TACE shall be reviewed in the tumor board after two treatment cycles.	**EC** **Quality objective:** Presentation at the tumor conference after TACE as often as possible

HBC 7: mRECIST-/EASL-classification after TACE

Numerator: Patients of the **Denominator** with assessment of remission by mRECIST or EASL classification. **Denominator:** All patients with HCC and TACE	3.72 Remission assessment after ablation/TACE/TARE shall be performed according to mRECIST/EASL.	**EC** **Quality objective:** Use the mRESCIST or EASL classification after TACE as often as possible.

HBC 8: Bridging Therapy

Numerator: Patients of the **Denominator** who have received bridging therapy.	3.42	**LoE 1** **Quality objective:** Bridging therapy as

Quality indicator	Underlying recommendation	Evidence base/ further information
Denominator: All patients with HCC (BCLC A), Child A on the transplant waiting list	Patients with HCC (BCLC A) within Milan criteria shall receive bridging therapy if liver function permits.	often as possible in patients with HCC (BCLC A) within the Milan criteria.
Notes: • Bridging: local ablation, resection, or transarterial procedures (TACE, TARE) • BCLC A: • ECOG (PS): 0-2 • Child-Pugh A to C • Singular tumor > 2cm or early multifocal disease with up to 3 tumors < 3cm		

HBC 9: Content of findings reports CCA

Numerator: Patients of the **Denominator** who have a histopathology report with the following information: • Staging (TNM classification) • Typing (WHO classification) • Grading • Resection margin (R classification) • For intrahepatic cholangiocarcinoma (C22.1): status of non-tumorous liver **Denominator:** All patients with CCA and resection or explantation	4.9 The processing and reporting of a resected specimen shall determine the extent of the tumor (staging) according to the current TNM classification, its type (typing) and degree of differentiation (grading), and the status of the resected margin (R classification), as well as the status of the non-tumorous liver in the case of intrahepatic cholangiocarcinomas. In the case of specimens with premalignant lesions, a possible transition to an invasive carcinoma shall be clarified by precise workup.	**EC** **Quality objective:** Complete diagnostic reports as often as possible
The **Numerator** is always a subset of the **Denominator**. * Indicator can be documented with the updated uniform basic oncology data set and the associated modules (as of 11.2020).		

11. Testicular cancer

(Version 1.1, February 2020)

Quality indicator	Reference Recommendation	Evidence base/ further information
Testis 1: Presentation tumor conference		
Numerator: Number of patients presented at an interdisciplinary tumour conference* after chemotherapy **Denominator:** All patients with germ cell tumor (ICD-10 C62) who have residual tumor after chemotherapy. Participants tumor conference: urology, pathology, radiology, hematooncology, radiotherapy, if required: visceral surgery	**4.2** CCT patients with post-chemotherapy residual tumors shall receive residual tumor resection only after prior multidisciplinary coordination and at centers with high expertise and the prerequisites for multidisciplinary surgical interventions.	**EC** **Quality Objective:** If possible, frequent therapy recommendation by an interdisciplinary tumor conference for patients with residual tumor after chemotherapy
Testis 2: Pathology report		
Numerator: Number of patients with all of the following in the pathodiagnostic report: Page Testicle size max. tumor size (in 3 dimensions) macroscopic features of the epididymis, spermatic cord and tunica vaginalis Tumor in the resection margin (yes/no) histological type with specification of individual components and percentage determination according to WHO 2016 peritumoral venous and/or lymphatic invasion (yes/no) Invasion of the tunica albuginea (yes/no) Invasion of the tunica vaginalis (yes/no)	**7.17** The pathodiagnostic report of the testicular specimen shall include the following statements: Indication of side, size of testis, maximum tumour size (in 3 dimensions), macroscopic features of epididymis, spermatic cord and tunica vaginalis, tumour in the resection margin (yes/no), histological type with specification of individual components and percentage determination according to WHO 2016, peritumoral venous and/or lymphatic invasion (yes/no), invasion of the tunica albuginea (yes/no), tunica vaginalis (yes/no), rete testis (yes/no), soft tissue of the hilar, epididymis or spermatic cord (yes/no), Germ cell neoplasia in situ in the non-tumorous parenchyma (yes/no), and pT category according to the TNM classification of 2017.	**LoE 2a** **Quality Objective:** Complete pathodiagnostic reports as often as possible.

Quality indicator	Reference Recommendation	Evidence base/ further information
Invasion of the rete testis (yes/no) Invasion of the soft tissue of the hilar, epididymis or spermatic cord (yes/no) Germ cell neoplasia in situ in non-tumorous parenchyma (yes/no) pT category according to the TNM classification of 2017 **Denominator:** All patients with an initial diagnosis of germ cell tumor (ICD-10 C62) and ablation of the testis.		

Testis 3: Offer cryopreservation

Numerator: Number of patients who were offered cryopreservation of spermatozoa pretherapeutically **Denominator:** All patients with initial diagnosis of germ cell tumor (ICD-10 C62) and therapy (surgery, radio- or chemotherapy)	**7.19** In cases of suspected CCT, cryopreservation of spermatozoa shall be offered before the start of therapy (before ablation of the testis, at the latest before chemotherapy or radiotherapy).	**LoE 5** **Quality Objective:** Pretherapeutic offer of cryopreservation of spermatozoa as often as possible.

Testis 4: Application of IGCCCG prognostic criteria

Numerator: Number of patients classified according to the IGCCCG prognostic criteria **Denominator:** All patients with metastatic germ cell tumor (ICD-10 C62, from stage II)	**8.5** Metastatic CCT shall be classified according to the prognostic criteria of the IGCCCG.	**EC** **Quality Objective:** If possible, frequent staging according to the IGCCCG prognostic criteria in patients with metastatic germ cell tumor.
Notes: - IGCCG 1997		

Testis 5: Active surveillance (seminoma)

Numerator:	**9.12**	**LoE 2b**

Quality indicator	Reference Recommendation	Evidence base/ further information
Number of patients with active monitoring **Denominator:** All patients with initial diagnosis of seminoma (ICD-O-M 9061/3) stage I (pT1-4, N0, M0)	Patients with seminoma in cSI shall be followed up with the surveillance strategy (Active Surveillance) and treated according to stage in case of recurrence.	**Quality Objective:** Active surveillance for follow-up of stage I seminoma patients as frequently as possible.

Testis 6: Active surveillance (non-seminomatous germ cell tumor)

Numerator: Number of patients with active monitoring **Denominator:** All patients with initial diagnosis of stage IA non-seminomatous germ cell tumor* (pT1, N0, M0, S0)	**9.15** In the low-risk situation, active monitoring shall be favoured.	**LoE 2b** **Quality Objective:** Active surveillance for follow-up of stage IA nonseminomatous germ cell tumor as frequently as possible.
Notes: *ICD-O morphology (3rd edition, 1st revision): non-seminomatous CCT: 9070/3, 9071/3, 9100/3, 9104/1, 9105/3, 9085/3, 9080/1, 9063/3, 8240/3, 9085/3, 9071/3, 8650/1, 8650/3, 8640/1, 8640/3, 8642/1, 8643/1, 8620/1, 8622/1, 8600/0, 8592/1, 8591/1, 9073/1		

Testis 7: System therapy stage IIC/III and good prognosis group

Numerator: Number of patients with 3 cycles of PEB (cisplatin, bleomycin, etoposide) over 5 days **Denominator:** All patients with germ cell tumor (ICD-10 C62) in stage IIC or III of the good prognosis group according to IGCCCG.	**9.30** Patients with metastatic CCT in stage IIC / III of the good prognosis group according to IGCCCG shall receive polychemotherapy with three cycles of PEB with application of cisplatin and etoposide over five days.	**LoE 1b** **Quality Objective:** If possible, frequent systemic therapy with 3 cycles of PEB over 5 days in patients in stage IIC/III of the good prognosis group.
Notes: • Contraindications to bleomycin shall be noted. Recommendation 9.34 and 9.38 apply to these patients. • IGCCG 1997		

Testis 8: System therapy metastatic seminoma and intermediate prognosis group

Numerator: Number of patients with four cycles of PEB (cisplatin, bleomycin, etoposide) **Denominator:** All patients with metastatic seminoma (ICD-O-M 9061/3; from stage II-IIIC) with intermediate prognosis according to IGCCCG.	**9.35** Patients with metastatic seminoma and intermediate prognosis are to receive four cycles of PEB chemotherapy.	**LoE 1b** **Quality Objective:** If possible, frequent systemic therapy with four cycles of PEB in metastatic seminoma and intermediate prognosis group
Notes: Contraindications to bleomycin shall be noted. For these patients, recommendation 9.36 applies. IGCCCG 1997		

Testis 9: System therapy non-seminomatous germ cell tumour and intermediate prognosis group

Numerator: Number of patients with four cycles of PEB (cisplatin, bleomycin, etoposide) **Denominator:** All patients with metastatic non-seminomatous germ cell tumor* (from stage II-IIIC) with intermediate prognosis according to IGCCCG.	**9.39** Patients with metastatic nonseminomatous CCT and intermediate prognosis shall receive four cycles of PEB chemotherapy.	**LoE 1b** **Quality Objective:** If possible, frequent systemic therapy with four cycles of PEB in non-seminomatous germ cell tumors and intermediate prognosis group.
Notes: • Contraindications to bleomycin shall be noted. For these patients, recommendation 9.40 applies. • *ICD-O morphology (3rd edition, 1.Revision): Non-seminomatous CCT: 9070/3, 9071/3, 9100/3, 9104/1, 9105/3, 9080/3, 9084/3, 9085/3, 9080/1, 9063/3, 9084/0, 8240/3, 9085/3, 9071/3, 8650/1, 8650/3, 8640/1, 8640/3, 8642/1, 8643/1, 8620/1, 8622/1, 8600/0, 8592/1, 8591/1, 9073/1. • IGCCG 1997		

Testis 10: System therapy non-seminomatous germ cell tumor and poor prognosis group.

Numerator: Number of patients with four cycles of PEB (cisplatin, bleomycin, etoposide) **Denominator:** All patients with metastatic non-seminomatous germ cell tumor* (from stage II-IIIC) with poor prognosis according to IGCCCG.	**9.41** Patients with metastatic non-seminomatous CCT and poor prognosis shall receive four cycles of PEB chemotherapy.	**LoE 1b** **Quality Objective:** If possible, frequent systemic therapy with four cycles of PEB in non-seminomatous germ cell tumors and poor prognosis group.

Notes:
- Contraindications to bleomycin shall be noted. For these patients, recommendation 9.42 applies.
- *ICD-O morphology (3rd edition, 1.Revision): Non-seminomatous CCT: 9070/3, 9071/3, 9100/3, 9104/1, 9105/3, 9080/3, 9084/3, 9085/3, 9080/1, 9063/3, 9084/0, 8240/3, 9085/3, 9071/3, 8650/1, 8650/3, 8640/1, 8640/3, 8642/1, 8643/1, 8620/1, 8622/1, 8600/0, 8592/1, 8591/1, 9073/1.
- IGCCG 1997

Testis 11: Residual tumor resection lung and retroperitoneum

Numerator: Number of patients with resection of the residual tumor **Denominator:** All patients with non-seminomatous CCT* and completed chemotherapy with S 0 (measurement time point approx. 6 weeks after end of chemotherapy) u Residual tumour >1cm in retroperitoneum and/or lung (axial CT diameter)	**9.70** After completion of primary chemotherapy and the achievement of marker normalization of a non-seminomatous CCT, residual tumors >1cm in the retroperitoneum and lung shall be resected. The management of residual tumours from other sites shall be decided on an individual basis.	**LoE 1b** **Quality Objective:** As often as possible adequate resection of residual non-seminomatous germ cell tumors after chemotherapy and normalization of serum markers.

Notes:
*ICD-O morphology (3rd edition, 1.Revision): Non-seminomatous CCT: 9070/3, 9071/3, 9100/3, 9104/1, 9105/3, 9080/3, 9084/3, 9085/3, 9080/1, 9063/3, 9084/0, 8240/3, 9085/3, 9071/3, 8650/1, 8650/3, 8640/1, 8640/3, 8642/1, 8643/1, 8620/1, 8622/1, 8600/0, 8592/1, 8591/1, 9073/1.

Quality indicators 2,3 and 11 are not to be documented with the basic oncology data set of the cancer registries (as of 10.2018)

12. Hodgkin lymphoma

(Version 3.0, October 2020)

Quality indicator	Reference Recommendation	evidence base/ further information
HL 1: Histological diagnosis		
Numerator: Number of patients with biopsy u/o excision LK **Denominator:** All patients with histological first diagnosis of Hodgkin lymphoma	**3.3** The histological diagnosis shall be made on the biopsy of a whole lymph node or other organ primarily affected.	**EC** **Quality Objective:** If possible, biopsy and/or excision of a lymph node (LK) for histological diagnosis when Hodgkin lymphoma is first diagnosed.
HL 2: Diagnostic requirements		
Numerator: Number of patients who received diagnostic tests BSG, CT (with contrast) of the neck, thorax and abdomen, X-ray thorax and bone marrow biopsy **Denominator:** All patients with a confirmed initial diagnosis of Hodgkin lymphoma	**3.7** Diagnostic examinations *shall* include history, physical examination, laboratory, imaging (CT (with contrast) of neck, thorax and abdomen, chest x-ray and PET/CT*. *CAVE: The PET examination is not part of the benefits catalogue of the statutory health insurance (cost coverage not guaranteed).	**EC** **Quality Objective:** Perform the above-mentioned diagnostic examinations as frequently as possible in patients with an initial diagnosis of Hodgkin's lymphoma.
Note: The **Numerator** is currently not compatible with the updated uniform oncological basic data set (= BDS) of the Association of German Tumour Centres (ADT) and the Association of Population Based Cancer Registries in Germany (GEKID) (as of 12.02.2014).		
HL 3: PET/CT in staging		
Numerator: Number of patients with PET/CT during staging **Denominator:** All patients with initial diagnosis of Hodgkin lymphoma	**3.14** PET/CT* shall be performed as part of staging for staging purposes.	**Quality Objective:** PET/CT shall be performed as often as possible as part of the staging process.
Note: The **Numerator** is currently not to be mapped with the updated uniform oncology basic data set (= BDS) (as of 12.02.2014).		

Quality indicator	Reference Recommendation	evidence base/ further information
HL 4: Interim PET/CT in advanced Hodgkin lymphoma		
Numerator: Number of patients with interim PET/CT **Denominator:** All patients with Hodgkin lymphoma stage III A o. B o stage IV A o. B u BEACOPP chemotherapy	**7.4** With the help of PET/CT* during ongoing chemotherapy (interim PET/CT), the individual response to therapy is to be determined at an early stage. Studies (GHSG HD18) have shown that FDG-PET/CT after 2 cycles of chemotherapy with BEACOPP allows selection of patients in whom further reduction of chemotherapy is possible.	**Quality Objective:** Interim PET/CT as often as possible in advanced Hodgkin lymphoma and BEACOPP chemotherapy
Note: The **Numerator** is currently not to be mapped with the updated uniform oncology basic data set (= BDS) (as of 12.02.2014).		
HL 5: BEACOPPescalated in advanced Hodgkin lymphoma*.		
Numerator: Number of patients with BEACOPP escalated **Denominator:** All adult patients up to 60 years of age with initial diagnosis of stage III A or B or stage IV A or B Hodgkin lymphoma.	**7.2** Adult patients up to 60 years of age with advanced HL *shall be* treated with BEACOPPescalated. **7.3** The number of cycles is based on the result of the interim staging by PET/CT* after 2 cycles. PET/CT-negative patients shall receive 2 further cycles of BEACOPPescalated, PET/CT-positive patients shall receive 4 further cycles, as before.	**Quality Objective:** Treatment with BEACOPPescalated as often as possible in advanced Hodgkin's lymphoma
HL 6: PET/CT after chemotherapy for advanced Hodgkin lymphoma		
Numerator: Number of patients with PET/CT according to BEACOPPescalated **Denominator:** All patients with initial diagnosis of Hodgkin lymphoma stage III A o. B or stage IV A o. B u BEACOPPescalated	**7.5** PET/CT* after therapy *will* be used to assess the individual response to chemotherapy.	**Quality Objective:** PET/CT as often as possible after BEACOPP chemotherapy in patients with advanced Hodgkin lymphoma
Note: The **Numerator** is currently not to be mapped with the updated uniform oncology basic data set (= BDS) (as of 12.02.2014).		

Quality indicator	Reference Recommendation	evidence base/ further information
HL 7: Radiation therapy for advanced Hodgkin's lymphoma*.		
Numerator: Number of patients with local radiotherapy (30 Gy) **Denominator:** All patients with initial diagnosis of Hodgkin lymphoma stage III A or B or stage IV A or B, BEACOP-escalated and with PET positive residual tumor.	**7.8** Patients who have responded to chemotherapy but show PET/CT-positive residual tissue shall receive local radiotherapy. **7.9** Patients in advanced stages who have received previous polychemotherapy and for whom there is an indication for additive radiotherapy shall be irradiated with a dose of 30 Gy.	**Quality Objective:** Local radiotherapy (30 Gy) as often as possible in patients with advanced Hodgkin lymphoma
Note: Positive residual tumor = not "no change" in BDS.		
HL 8: Confirmation of diagnosis in recurrence of NLPHL*.		
Numerator: Number of patients with LK biopsy to confirm diagnosis **Denominator:** All patients with recurrence of NLPHL	**8.19** Patients with NLPHL suspected of recurrence shall be re-diagnosed by lymph node biopsy due to the risk of transformation of NLPHL into aggressive non-Hodgkin lymphoma.	**EC** **Quality Objective:** LK biopsy as often as possible to confirm the diagnosis in patients with recurrence of NLPHL
HL 9: Recurrence therapy for Hodgkin's lymphoma*.		
Numerator: Number of patients with autologous stem cell transplantation **Denominator:** All patients up to 60 years with 1st relapse or progression of Hodgkin lymphoma	**9.7** Patients up to 60 years of age without severe comorbidities shall receive high-dose chemotherapy with autologous stem cell transplantation in case of relapse or progression of Hodgkin lymphoma.	**Quality Objective:** Autologous stem cell transplantation as often as possible in patients up to 60 years of age with 1st relapse or progression of Hodgkin lymphoma
Notes: *CAVE: The PET examination is not part of the benefits catalogue of the statutory health insurance (cost coverage not guaranteed).		

13. Colorectal carcinoma

(Version 2.1, January 2019)

Quality indicator	Reference Recommendation	Evidence base/ further information
CRC 1: Collection of family history		
Numerator: Number of patients with completed patient questionnaire **Denominator:** All patients with initial diagnosis of CRC	**None** Justification of this QI: The analysis of international QI (here mainly ASCO) has shown that internationally, QI for the recording of the family history are described. The guideline group considers the area to be relevant, so that it defines a QI without an accompanying strong recommendation in the guideline.	**Quality Objective:** Completing the patient questionnaire as often as possible to obtain family history.
Note: Patient Questionnaire: https://www.krebsgesellschaft.de/zertdokumente.html?file=files/dkg/deutsche-krebsgesellschaft/content/pdf/Zertifizierung/Erhebungs-%20und%20Kennzahlenboegen/PatientenFragebogen%20familiaerer%20Darmkrebs%20%2803032017%29.pdf		
CRC 2: Complete reports of findings after tumor resection for CRC		
Numerator: Number of patients with report of findings with indication of: Tumour type according to WHO classification Tumour invasion depth (pT classification) Status of the regional lymph nodes (pN classification) Number of lymph nodes examined Grading Distance from the resection margins (for rectal carcinoma also circumferential) R-Classification **Denominator:** All patients with CRC and surgical resection	**7.58** The following information by the pathologist is required: Tumour type according to WHO classification (Evidence 1c) Tumour invasion depth (pT classification) (Evidence 1c) Status of the regional lymph nodes (pN classification) (Evidence 1c) Number of lymph nodes examined (Evidence 2a) Grading (Evidence 2a) Distance from the resection margins (for rectal cancer also circumferential) (Evidence 2a) R-classification (Evidence 1c)	**Quality Objective:** Complete reports of findings after tumour resection in CRC as often as possible

Quality indicator	Reference Recommendation	Evidence base/ further information
CRC 3: Mutation determination in mKRK		
Numerator: Number of patients with RAS (= KRAS and NRAS mutations) and BRAF mutations at the start of first-line therapy **Denominator:** All patients with mKRK and first-line therapy	**9.4** The determination of (ALL) RAS and BRAF mutations shall be performed prior to initiation of first-line therapy, if possible.	**LoE 1** **Quality Objective:** Mutation determination as often as possible before first-line therapy in mKRK.
Notes: Definition "at start" = date of mutation determination max. +15d from date of start of first-line therapy		
CRC 4: Combination chemotherapy for mKRK		
Numerator: Number of patients with combination chemotherapy **Denominator:** All patients with mKRK, ECOG 0-1 and first-line systemic therapy.	**9.24** In first-line chemotherapy, fluoropyrimidine-based combination regimens with infusional administration of 5-fluorouracil, such as FOLFIRI, FOLFOX or FOLFOXIRI, or with the oral fluoropyrimidine capecitabine (predominantly with oxaliplatin, CAPOX) shall be used in the first instance if the patient is in good general condition and highly motivated.	**LoE 1a** **Quality Objective:** Combination chemotherapy as often as possible in first-line therapy of patients with mKRK, ECOG 0-1
CRC 5: Indication of distance mesorectal fascia		
Numerator: All patients with indication of the distance to the mesorectal fascia in the findings report **Denominator:** All patients with rectal cancer and MRI or thin-slice CT of the pelvis.	**7.17** The description of findings shall include a statement about the distance to the mesorectal fascia.	**EC** **Quality Objective:** If possible, frequently indicate the distance of the mesorectal fascia if an MRI/CT was performed for rectal cancer.

Quality indicator	Reference Recommendation	Evidence base/ further information
CRC 6: Quality TME		
Numerator: Number of all patients with good or moderate quality (grade 1: mesorectal fascia preserved or grade 2: intramesorectal tears) TME. **Denominator:** All patients with radically operated rectal cancer	**7.66** Since the quality of a surgical resection, taking into account the above categories, allows conclusions to be drawn regarding the prognosis for the development of a local recurrence, it is obligatory to describe this in the pathohistological findings report as follows The quality of the preparation is judged by the integrity of the mesorectal fascia in case of resection with the 3 categories: • Preserve mesorectal fascia • Intramesorectal tears • Reaching the muscularis propria or tumor. In the case of rectal extirpation, preparation tears and a tumor-positive circumferential safety margin are less common with complete resection of the levator muscles. In the patho-diagnostic report, the description of the radicality in the area of the levator musculature is therefore obligatory. The following categories shall be used for this purpose: • Parts of the muscularis propria are missing or opening of the intestine or tumor • Muscularis propria preserved, no opening of the intestine or tumor • Levator muscles also resected, no opening of the intestine or tumor These assessments are to be made by the pathologist.	**EC** **Quality Objective:** As often as possible good or moderate quality of TME in rectal carcinoma

Quality indicator	Reference Recommendation	Evidence base/ further information
CRC 7: Presentation of tumor conference		
Numerator: Number of patients presented pre-therapeutically in an interdisciplinary tumor conference **Denominator:** All patients with rectal carcinoma and all patients with colon carcinoma stad. IV	**7.1** All patients with CRC shall be presented in an interdisciplinary tumor conference after completion of primary therapy (e.g. surgery, chemotherapy). Already pre-therapeutically, patients shall be presented in the following constellations **Denominator**: - with rectal cancer - with colon carcinoma, stage IV - with metachronous distant metastases - with local recurrences - before any local ablative procedure RFA/LITT/SIRT	**EC** **Quality Objective:** Patients with rectal cancer and patients with colon cancer stad. IV in the pre-therapeutic tumor conference
CRC 8: Adjuvant chemotherapy		
Numerator: Number of patients who received adjuvant chemotherapy. **Denominator:** All patients with UICC stage III colon cancer who underwent R0 resection of the primary tumor.	**8.4** Adjuvant chemotherapy is indicated for patients with R0 resected stage III colon cancer.	**LoE 1a** **Quality Objective:** Adequate performance of adjuvant chemotherapy after R0 resection colon cancer stad. III

CRC 9: Anastomosis insufficiency rectal cancer

Numerator: Number of patients with anastomosis insufficiency grade B (with antibiotic administration or interventional drainage or transanal lavage/drainage) or C (re-)laparotomy) after elective surgery. **Denominator:** All patients with rectal cancer in whom an anastomosis was created in an elective primary tumor resection.	**None** Justification of this QI: Notes: The Guideline Commission decided that not only structural quality objectives but also outcome quality objectives shall be taken into account. This results in the inclusion of this indicator in the guideline even without a consensual strong recommendation.	Since this indicator was not derived from a strong recommendation, evidence base does not apply. **Quality Objective:** Grade B or C anastomosis insufficiencies after anastomosis creation in operated rectal carcinoma are as rare as possible.

CRC 10: Anastomotic insufficiency Colon carcinoma

Numerator: Re-intervention of anastomotic insufficiencies of the colon after elective surgery **Denominator:** All patients with colon carcinoma in whom an anastomosis was created in an elective tumor resection.	**None** Justification of this QI: Notes: The Guideline Commission decided that not only structural quality objectives but also outcome quality objectives shall be taken into account. This results in the inclusion of this indicator in the guideline even without a consensual strong recommendation.	Since this indicator was not derived from a strong recommendation, evidence base does not apply. **Quality Objective:** Anastomosis insufficiencies requiring re-intervention as seldom as possible G after anastomosis creation in operated colon carcinoma

CRC 11: Marking of stoma position

Numerator: Number of patients with preoperative marking of the stoma position **Denominator:** All patients with rectal carcinoma who underwent surgery with a stoma.	**7.42** The stoma position shall be marked preoperatively.	**EC** **Quality Objective:** Preoperative marking of the stoma position as often as possible

14. Laryngeal Cancer

(Version 1.1, November 2019)

Quality indicator	Reference Recommendation	Evidence base / further information
Larynx 1: Report of findings after tumor resection and lymph node removal		
Numerator: Number of patients with reports of findings indicating: • Tumor location (ICD-O-3 topography) and size (in mm), • histological tumor type (WHO classification), • local tumor extension u infiltrated structures (cT/pT), • Lymph node metastases (cN/pN) separated by level and side: • Number of LCs examined, • Number of affected LK, • largest diameter of the lymph node metastases • supravascular tumor • Lymphatic/venous invasion and perineural invasion (L, V, Pn), • Presence of an in situ component (cTis/pTis, with mm size), • Differentiation of the tumor according to the established grading scheme (G1-4) • Distance to lateral and basal resection margins for all relevant resection margins as well as for the invasive and the in	**4.4.** The following parameters shall be specified: Tumor location and size, histological tumor type according to the current WHO classification, local tumor extension, infiltrated structures, Lymph node metastases separated by level and side: • Number of LCs examined, • Number of affected LK, • largest diameter lymph node metastases, • supravascular tumor • Lymphatic/venous invasion and perineural invasion, • Presence of an in situ component (with size), • Differentiation of the tumor according to the established grading scheme • Distance to lateral and basal resection margins for all relevant resection margins as well as for the invasive and in situ components.	**EC** **Quality Objective:** Complete reports of findings after tumor resection and lymph node removal as often as possible

Quality indicator	Reference Recommendation	Evidence base / further information
situ component (specify: yes/no) **Denominator:** All patients with laryngeal carcinoma and tumour resection and lymph node removal		

Larynx 2: Performance of panendoscopy

Numerator: Number of patients with panendoscopy **Denominator:** All patients with initial diagnosis of laryngeal carcinoma	**6.7.** Panendoscopy shall be performed in patients with laryngeal carcinoma.	**EC** **Quality Objective:** Panendoscopy shall be performed as often as possible when laryngeal carcinoma is first diagnosed.

Larynx 3: Pretherapeutic tumor conference

Numerator: Number of patients who were discussed pre-therapeutically in the TK **Denominator:** All patients with laryngeal carcinoma	**7.1** The treatment of laryngeal carcinoma shall be carried out in an interdisciplinary manner after coordination of each individual case within tumour boards involving the specialist disciplines of otorhinolaryngology, radiotherapy, medical oncology, pathology and radiology.	**EC** **Quality Objective:** Presentation of patients in the pre-therapeutic tumor conference as often as possible

Larynx 4: Postoperative radiochemotherapy

Numerator: Number of patients with postoperative radiochemotherapy **Denominator:**	**7.38.** Postoperative radiochemotherapy shall be perfomed: • with R1 or resection margin <5mm in the area of the mucosa in the tumor parts	**LoE 1b** **Quality Objective:** If possible, frequent postoperative radiochemotherapy for resection margin <5mm or R1or pN3b

Quality indicator	Reference Recommendation	Evidence base / further information
All patients with initial diagnosis of laryngeal carcinoma and resection with resection margins <5mm or R1 or extracapsular LK growth (pN3b).	not surrounded by cartilage or • in case of extracapsular tumor growth at the lymph nodes	

Larynx 5: R0 resection

Numerator: Number of patients with final surgical result R0 **Denominator:** All patients with initial diagnosis of laryngeal carcinoma and resection	**7.54.** The aim of the surgical procedure shall be an R0 resection. If R0 resection does not appear possible, primary surgical therapy shall not be performed. In the case of R1, a resection shall be attempted.	**EC** **Quality Objective:** As often as possible R0 as final resection result after resection

Larynx 6: Consultation with speech therapist/linguist

Numerator: Number of patients with advice from speech therapists/speech scientists **Denominator:** All patients with initial diagnosis of laryngeal carcinoma and therapy	**7.69.** Even before the start of tumor therapy, the subsequent voice function shall be considered. Patients shall be informed about the various rehabilitation options with the involvement of speech therapists and care givers of patient support groups.	**EC** **Quality Objective:** Consultation with speech therapist/linguist as often as possible before therapy

The quality indicators 1,2, 4 and 6 cannot be compared with the basic data set of the Association of German Tumour Centres (ADT) and the Association of Population Based Cancer Registries in Germany (GEKID) (as of 12.02.2014).

15. Lung Cancer

(Version 1.0, February 2018)

Quality indicator	Reference Recommendation	Evidence base/ further information
Lung 1: Molecular pathological examination in patients NSCLC stage IV with adenocarcinoma or adenosquamous carcinoma		
Numerator: Number of patients with EGFR mutations in exons 18-21 and/or ALK fusions and/or ROS1 fusions **Denominator:** All patients with initial diagnosis of adenocarcinoma or adenosquamous carcinoma of the lung stage IV	**6.59 Molecular pathological examinations** On the basis of the available tumor tissue / tumor cells of all non curatively treatable non squamous cell NSCLC, molecular pathological investigations shall be initiated with regard to all therapeutically relevant molecular alterations (according to the current status before first-line therapy as a minimum requirement EGFR mutations in exons 18-21, ALK fusions and ROS1 fusions, BRAF V600 mutations). This also applies to squamous cell carcinomas of never smokers/light smokers.	**EC** **Quality Objective:** If possible, frequent examination of at least EGFR mutations in exons 18-21 and/or ALK fusions and/or ROS1 fusions in patients with initial diagnosis of adenocarcinoma and adenosquamous Ca of the lung stage IV.
Lung 2: First-line therapy with EGFR TKIs in patients NSCLC stage IV with activating EGFR mutation and ECOG 0-2.		
Numerator: Number of patients with initiation of first-line therapy with EGFR TKIs **Denominator:** All patients with initial diagnosis of NSCLC stage IV, activating EGFR mutation and ECOG 0-2	**7.29 First-line therapy** In the presence of an activating EGFR mutation, patients with ECOG 0-2 shall be offered an EGFR TKI in first-line therapy.	**LoE 1a** **Quality Objective:** First-line therapy with EGFR-TKI as often as possible for activating EGFR mutation in NSCLC stage IV with ECOG 0-2
Note: Based on TNM classification 8th edition, 2017 [1]		

Lung 3: First-line ALK-specific TKI therapy in patients with stage IV ALK-positive NSCLC.

Numerator: Number of patients with initiation of ALK-specific TKI therapy **Denominator:** All patients with initial diagnosis NSCLC stage IV, ALK pos.	**7.38 First-line therapy in chemotherapy-naïve patients** Crizotinib to be offered in the first-line treatment of ALK positive NSCLC patients	**LoE 1b** **Quality Objective:** If possible, ALK-specific TKI therapy as first-line therapy in ALK-pos. NSCLC stage IV
Note: Based on TNM classification 8th edition, 2017 [1]		

Lung 4: First-line ROS1-specific TKI therapy in patients with ROS1-positive stage IV NSCLC.

Numerator: Number of patients with initiation of ROS1-specific TKI therapy **Denominator:** All patients with initial diagnosis of NSCLC stage IV, ROS1- positive	**7.43 System therapy in patients with ROS1 fusion genes (ROS1 + NSCLC)** For patients with ROS1 fusion genes (ROS1 + NSCLC), crizotinib shall be offered in first-line therapy.	**LoE 1b** **Quality Objective:** If possible, ROS1-specific TKI therapy as first-line therapy in ROS1-pos. NSCLC stage IV
Note: Based on TNM classification 8th edition, 2017 [1]		

Lung 5: Pretherapeutic presentation Tumor conference

Numerator: Number of patients presented pre-therapeutically in the interdisciplinary tumor conference **Denominator:** All patients with NSCLC stage IVA	**7.51 Therapy in "new proposed stage IVA (IASLC 2016/17)".** Patients with "new proposed stage IVA (IASLC 2016/17)" (M1a and M1b descriptors) shall receive a multimodality treatment decision by consensus in an interdisciplinary tumor conference.	**EC** **Quality Objective:** Pretherapeutic presentation at the interdisciplinary tumor conference for stage IVA NSCLC as often as possible.
Note: Participants TK: oncology, pneumology, radiotherapy, surgery, possibly + radiology and nuclear medicine and localization-related disciplines (e.g. neurosurgery, visceral surgery). Based on the TNM classification 8th edition, 2017 [1]		

Lung 6: Adjuvant cisplatin-based chemotherapy for stage II - IIIA1/A2 NSCLC.

Numerator: Number of patients receiving adjuvant chemotherapy with	**Recommendation 8.20** After R0 resection and systematic lymph node dissection, patients in stage II or IIIA1/A2 (see Chapter 8.5.1)	**LoE 1a-2b** **Quality Objective:** If possible, adjuvant cisplatin-based chemotherapy for

cisplatin-based combinations **Denominator:** All patients with initial diagnosis of NSCLC stage II or IIIA1/A2, ECOG 0/1, R0 resection and lymph node dissection.	in good general condition (ECOG 0/1) shall receive adjuvant chemotherapy. **Chapter 8.5.2.1.5** Adjuvant chemotherapy is recommended in stage IIIA with incisional N2 status (IIIA1/A2) after complete resection (R0) and systematic lymph node dissection.	stage II or IIIA1/A2 NSCLC with ECOG 0/1.
Note: The recommendation is based on the TNM classification 7th edition, 2010 [2]. With the TNM classification 8th edition, 2017, there is no change of the QI		

Lung 7: Combined radiochemotherapy for stage IIIA4/IIIB NSCLC

Numerator: Number of patients with radiochemotherapy **Denominator:** All patients with initial diagnosis of NSCLC stage IIIA4 or IIIC and ECOG 0/1	**7.4.4** Patients in stage IIIA4 / IIIB shall receive a combination of radiotherapy and chemotherapy, if the general condition and tumor extension allow it.	**LoE 1b** **Quality Objective:** If possible, radiochemotherapy for NSCLC stage IIIA4 or IIIC and ECOG 0/1
Note: The recommendation is based on the TNM classification 7th edition, 2010 [2]. With the TNM classification 8th edition, 2017, stage IIIC was added for the QI.		

Lung 8: Combined radiochemotherapy for SCLC stad. IIB - IIIB

Numerator: Number of patients with radiochemotherapy **Denominator:** All patients with initial diagnosis of SCLC stage IIB[T3] - IIIC [TNM: cT1/2 N2-3 M0, cT3/4 N0-3 M0] and ECOG 0/1	**8.5.2** Patients with radiation-eligible tumor spread of small cell lung carcinoma shall receive early combined chemoradiation therapy whenever possible	**LoE 2a** **Quality Objective:** If possible, radiochemotherapy for SCLC stage IIB-IIIC, ECOG 0/1
Note: The recommendation is based on the TNM classification 7th edition, 2010 [2]. With the TNM classification 8th edition, 2017 the stage IIIC was added for the QI.		

16. Gastric Cancer

(Version 2.0, August 2019)

Quality indicator	Reference Recommendation	Evidence base/ further information

Preliminary remarks: Tumors whose center is > 2 cm from the esophagogastric junction are classified as gastric carcinomas, even if the esophagogastric junction is involved.

GastrCa 1: Full pathology report

Numerator: Number of patients with at least the following information in the pathohistological findings report: • Type of material removed, • Tumor localization (macroscopic / microscopic), • minimal removal of the tumor to the resection margins, • Size of the tumor, • microscopic tumor type (according to current WHO classification), • Grading[a] (current WHO classification), • TNM classification (indicating the examined and affected lymph nodes), • R-Classification. a: possibly omitted after neoadj therapy **Denominator:** All patients with carcinoma of the stomach or esophagogastric junction (ICD-10 C16.[01], C16.1-16.9) and surgical resection.	**8.2** The pathological-anatomical assessment shall be complete and in a standardised form (see information in the background text).	**EC** **Quality Objective:** As often as possible complete pathodiagnostic reports after surgical resection of a carcinoma of the stomach or the esophagogastric junction.

GastrCa 2: Endoscopic en-bloc resections

Numerator:	**9.1**	**9.1: LoE 3b; 9.2: EC** **Quality Objective:**

Quality indicator	Reference Recommendation	Evidence base/ further information
Number of patients with en bloc resection **Denominator:** All patients with carcinoma of the stomach or esophagogastric junction (ICD-10 C16.[01], C16.1-16.9) and endoscopic resection.	Intraepithelial neoplasms (so-called dysplasias) of any size as well as early gastric carcinomas that fulfill all four of the following criteria shall be resected endoscopically en bloc: < 2cm diameter unulcerated Mucosal carcinoma intestinal type or histological degree of differentiation good or moderate (G1/G2) **9.3** Endoscopic resection of early gastric carcinoma shall be performed as a complete en bloc resection, allowing complete histologic evaluation of the lateral and basal margins.	En bloc resections as frequently as possible for endoscopic resection of carcinoma of the stomach or esophagogastric junction .

GastrCa 3: R0 resections (endoscopy) *

Numerator: Number of patients with R0 resection after completed endoscopic therapy **Denominator:** All patients with carcinoma of the stomach or esophagogastric junction (ICD-10 C16.[01], C16.1-16.9) and endoscopic resection.	**9.1** Intraepithelial neoplasms (so-called dysplasias) of any size as well as early gastric carcinomas that fulfill all four of the following criteria shall be resected endoscopically en bloc: • < 2cm diameter • non-ulcerated • Mucosal carcinoma • intestinal type or histological degree of differentiation good or moderate (G1/G2) **9.3** Endoscopic resection of early gastric carcinoma shall be performed as a complete en bloc resection, allowing complete histologic evaluation of the lateral and basal margins.	**9.1: LoE 3b; 9.2: EC** **Quality Objective:** As often as possible R0 situations after endoscopic resection of gastric carcinoma or carcinoma of the esophagogastric junction.

Quality indicator	Reference Recommendation	Evidence base/ further information
GastrCa 4: Nutritional status		
Numerator: Number of patients with determination of nutritional status according to Nutritional Risk Score and Body Mass Index **Denominator:** All patients with carcinoma of the stomach or esophagogastric junction (ICD-10 C16.0, C16.1-16.9)	**14.2** Nutritional status shall be assessed in all tumor patients, beginning with diagnosis, at every inpatient admission and outpatient contact, in order to be able to initiate interventions at an early stage.	**EC** **Quality Objective:** If possible, survey nutritional status frequently in patients with carcinoma of the stomach or esophagogastric junction.
GastrCa 5: Anastomotic insufficiency grade III		
Numerator: Number of patients with grade III anastomosis insufficiency **Denominator:** All patients with carcinoma of the stomach or esophagogastric junction (ICD-10 C16.0, C16.1-16.9) and resection with reconstruction by anastomosis.	**Specific guideline objective:** Detection of anastomotic insufficiency grade III (localized defect requiring surgical therapy) after gastrectomy.	**Quality Objective:** Rarely possible grade III anastomotic insufficiencies after resection with reconstruction by anastomosis in patients with carcinoma of the stomach or esophagogastric junction.
Notes: Classification of anastomotic insufficiency into I-III. I: locally defect, no change in therapy, only medicaments or diet modification II: Localized defect requiring intervention, but no surgery, e.g. IR drain, stent or bedside opening III: Localized defect requiring surgical therapy (according to: Low, D.E., et al, International Consensus on Standardization of Data Collection for Complications Associated With Esophagectomy: Esophagectomy Complications Consensus Group (ECCG). Ann Surg, 2015 Aug;262(2):286-94)		

GastrCa 6: Vitamin B12 substitution after gastrectomy

Numerator: Number of patients with documented recommendation for vitamin B12 substitution (e.g. 1000µg every 3 mo) in the medical report **Denominator:** All patients with carcinoma of the stomach or esophagogastric junction (ICD-10 C16.0, C16.1-16.9) after gastrectomy	**15.3** After gastrectomy, regular parenteral vitamin B12 substitution shall be performed throughout life.	**EC** **Quality Objective:** Recommendation and implementation of vitamin B12 substitution as often as possible after gastrectomy in patients with carcinoma of the stomach or esophagogastric junction.

GastrCa 7: Perioperative chemotherapy for gastric carcinomas cT3 and cT4, M0*

Numerator: Number of patients with preoperative chemotherapy **Denominator:** All patients with initial diagnosis of gastric carcinoma (ICD-10 16.1-16.9) cT3 or cT4, M0 and resection	**11.2** For localized gastric carcinoma of categories cT3 and resectable cT4 tumors, perioperative chemotherapy, i.e., shall be started preoperatively and continued postoperatively.	**LoE 1a** **Quality Objective:** Preoperative chemotherapy as often as possible for localized gastric carcinoma cT3 or cT4, M0 with resection.

GastrCa 8: Perioperative chemotherapy or radiochemotherapy for adenocarcinoma of the esophagogastric junction with cT3 or cT4, M0

Numerator: Number of patients with preoperative chemotherapy or radiochemotherapy **Denominator:** All patients with adenocarcinoma of the esophagogastric junction (ICD-10 16.^{01}) cT3 or cT4, M0 and resection	**11.3** For non-remote metastatic adenocarcinoma of the esophagogastric junction of categories cT3 and resectable cT4 tumors, neo-adjuvant radiochemotherapy or perioperative chemotherapy shall be performed.	**LoE 1a** **Quality Objective:** If possible, frequent perioperative chemotherapy or radiochemotherapy for adenocarcinomas of the esophagogastric junction cT3 or cT4, M0 and resection.

GastrCa 9: Presentation of interdisciplinary tumor conference*

Numerator: Number of patients with post-interventional presentation in the tumor conference **Denominator:** All patients with carcinoma of the stomach or esophagogastric junction (ICD-10 C16.[01], C16.1-16.9) with surgical therapy (endoscopic or surgical resection)	**11.9** If tumor progression is detected, the decision on further therapy shall be made on an interdisciplinary basis. 11.**12** After preoperative chemotherapy and subsequent surgery, postoperative chemotherapy shall be decided on an interdisciplinary basis.	**EC** **Quality Objective:** Post-interventional presentation in the interdisciplinary tumor conference of patients with carcinoma of the stomach or esophagogastric junction with surgical therapy (endoscopic or surgical resection) as often as possible.

GastrCa 10: Determination of HER-2 status before palliative tumor therapy

Numerator: Number of patients with determination of HER-2 status **Denominator:** All patients with carcinoma of the stomach or esophagogastric junction (ICD-10 C16.[01], C16.1-16.9) with palliative medical tumor therapy.	**12.6** Prior to the use of palliative medical tumor therapy, HER-2 status shall be determined as a positive predictive factor for therapy with trastuzumab.	**EC** **Quality Objective:** Determination of HER-2 status as frequently as possible prior to palliative drug therapy in patients with carcinoma of the stomach or esophagogastric junction.

* Indicator can be documented with the updated uniform basic oncology data set and the associated modules (as of: July 2019)

17. Breast Cancer

(Version 4.3, February 2020)

Quality indicator	Reference Recommendation	Evidence base/ further information
MamCa 1: Further treatment of breast carcinomas detected in screening in certified breast cancer centres		
Numerator: Number of patients receiving treatment in a certified breast cancer centre (DKG/DGS, NRW) **Denominator:** All patients detected in the screening with histologically confirmed inv MaCa u/o DCIS	**3.9.** d.) In order to ensure the best possible treatment, further therapy of breast carcinoma detected in screening shall take place in certified breast centres. Continuous quality assurance shall be ensured through communication and data collection between the screening centre and the certified breast centre.	**EC** **Quality Objective:** If possible, further treatment of breast carcinomas and/or DCIS detected in screening at a certified breast cancer centre.
Note: The QI can be evaluated with data from the cooperative mammography association		
MamCa 2: Pretherapeutic histological confirmation		
Numerator: Patients with pre-therapeutic histological diagnosis confirmation by punch or vacuum biopsy **Denominator:** Patients with first intervention and histology "invasive breast carcinoma or DCIS" as primary disease	**4.5.** Histological clarification of findings shall be performed by punch biopsy, vacuum biopsy and, in exceptional cases to be justified, by open excision biopsy.	**LOE 3a** **Quality Objective:** As many patients as possible with pre-therapeutic histological confirmation by punch or vacuum biopsy in the case of initial intervention and primary disease invasive breast carcinoma and/or DCIS.
MamCa 3: Intraoperative preparative radiography/sonography		
Numerator: Operations with intraoperative preparative X-ray or intraoperative preparative sonography **Denominator:** Operations with preoperative wire marking controlled by mammography or sonography	**4.6.** Pre- or intraoperative marking shall be carried out, particularly in the case of non-palpable changes, using the method with which the finding can be clearly visualised. The proof of an adequate resection is to be provided intraoperatively by preparation radiography or preparation sonography. If MR-guided marking has been performed, an MR control shall be performed within 6 months in case	**EC** **Quality Objective:** As often as possible intraoperative preparation ultrasonography or radiography after preoperative marking

Quality indicator	Reference Recommendation	Evidence base/ further information
	of histologically unspecific benign findings.	

MamCa 4: Axillary lymph node removal for DCIS

Numerator: Patients with axillary lymph node removal (primary axillary dissection or SNB) **Denominator:** Patients with histology "DCIS" and completed surgical therapy for primary disease and breast-conserving therapy	**4.10.** Axillary dissection shall not be performed for DCIS. A sentinel node biopsy shall only be performed if a secondary sentinel node biopsy is not possible for technical reasons, e.g. in the case of ablatio mammae.	**LOE 1b** **Quality Objective:** As few patients as possible with primary axillary dissection or sentinel node biopsy (SNB) in DCIS with breast-conserving therapy
Note: Quality Objective <5%		

MamCa 5: Endocrine therapy as the first therapeutic option in steroid receptor-positive metastatic breast carcinoma

Numerator: Patients who have received endocrine-based therapy in the metastatic stage as first-line therapy. **Denominator:** All patients with steroid-receptor-positive and HER2-negative breast carcinoma and initial diagnosis of metastasis.	**5.13.** Endocrine therapy +/- targeted therapy is the treatment of choice in patients with positive hormone receptor status and negative HER2 status. Endocrine therapy is not indicated in patients with the need to achieve rapid remission to avert pronounced symptoms of the affected organ.	**LOE 1b** **Quality Objective:** Endocrine-based therapy as first-line therapy in patients with breast carcinoma, positive hormone receptor status, negative HER2 status and first diagnosis of metastasis.

MamCa 6: Indication for sentinel lymph node biopsy

Numerator: Patients with sentinel node biopsy alone **Denominator:** Patients with primary disease invasive breast carcinoma and negative pN staging and without preoperative tumor-specific therapy	**4.23.** a.) Axillary staging shall be part of the surgical therapy of invasive breast carcinoma. Consensus b.) This shall be done with the help of sentinel lymph node removal (SNB) with palpatory and sonographically unremarkable lymph node status.	**EC** **Quality Objective:** As many patients as possible with sentinel node biopsy in lymph node-negative (pN0) invasive breast carcinoma without preoperative tumor-specific therapy.
Note: The quality indicator shall be calculated separately for female and male patients (see introduction).		

Quality indicator	Reference Recommendation	Evidence base/ further information
MamCa 7: Therapy of the axillary lymph drainage areas in pN1mi		
Numerator: Number of patients with therapy (= axillary dissection or radiotherapy) of the axillary lymph drainage areas **Denominator:** All patients with primary disease invasive breast carcinoma, pN1mi	**4.23.** f.) In the case of exclusive micrometastasis, targeted therapy of the lymph drainage areas (surgery, radiotherapy) should be avoided.	**LoE 1b** **Quality Objective:** Therapy of the axillary lymph drainage areas in the case of micrometastasis as rarely as possible
Note: Quality Objective <5%		
MamCa 8: Radiation therapy performed after BET		
Numerator: Patients with invasive carcinoma and BET who have received breast radiotherapy. **Denominator:** Patients with primary disease invasive breast carcinoma and BET	**4.36.** After breast-conserving surgery for invasive carcinoma, radiation of the affected breast shall be performed. In patients with clearly limited life expectancy (<10 years) and a small (pT1), nodal-negative (pN0), hormone receptor-positive HER2-negative tumor with endocrine adjuvant therapy, provided that the incision margins are free, radiotherapy may be omitted after individual consultation, provided that an increased risk of local recurrence is accepted.	**LOE 1a** **Quality Objective:** Adequate rate of radiotherapy after BET in patients with initial invasive breast carcinoma.
MamCa 9: Endocrine therapy for receptor-positive findings		
Numerator: Patients who have received adjuvant endocrine therapy. **Denominator:**	**4.50.** a.) Patients with estrogen and/or progesterone receptor positive (°) invasive tumors shall receive endocrine therapy.	**LOE 1a** **Quality Objective:** Endocrine therapy shall be carried out as often as possible in receptor-positive patients with invasive breast carcinoma.

Quality indicator	Reference Recommendation	Evidence base/ further information
Steroid receptor positive patients with primary disease invasive breast carcinoma.	° (>/=10% progesterone receptor-positive tumor cell nuclei)	

MamCa 10: Trastuzumab therapy in HER2-positive patients

Numerator: All patients who have received (neo-) adjuvant trastuzumab therapy for more than 1 year. **Denominator:** All HER2-positive (immunohistochemical score 3+ and/or ISH-positive) patients with primary disease invasive breast carcinoma >= pT1c	**4.63.** a.) Patients with HER2-overexpressing tumours with a diameter ≥ 1 cm (immunohistochemical score 3+ and/or ISH-positive) shall receive (neo-)adjuvant treatment with anthracycline followed by a taxane in combination with trastuzumab. Trastuzumab is to be administered for a total duration of one year.	**LOE 1b** **Quality Objective:** If possible, frequent trastuzumab therapy for 1 year in HER2-positive patients with invasive breast carcinoma >= pT1c

18. Melanoma

(Version 3.3, July 2020)

Quality indicator	Reference Recommendation	Evidence base/ further information
MEL 1: Safety distance (1 cm) for radical excision		
Numerator: Patients with radical excision with safety distance 1 cm **Denominator:** Patients with a primary cutaneous melanoma and curative radical excision with a tumour thickness ≤ 2 mm	**4.8** For malignant melanoma, a radical excision with the safety distances to the tumor margin shall be performed under curative intention to avoid local recurrences of the tumor. *Stage:* pT1, pT2 *Tumour thickness according to Breslow:* ≤ 1-2 mm *Safety distance:* 1cm	**LoE 1a** **Quality Objective:** As often as possible safety distance 1cm in curative radical excision of a melanoma with tumour thickness ≤ 2 mm
MEL 2: Safety distance (2 cm) for radical excision		
Numerator: Patients with radical excision with safety distance 2 cm **Denominator:** Patients with a primary cutaneous melanoma and curative radical excision with a tumour thickness > 2 mm	**4.8** For malignant melanoma, a radical excision with the safety distances to the tumor margin shall be performed under curative intention to avoid local recurrences of the tumor. *Stage:* pT3, pT4 *Tumor thickness according to Breslow:* 2.01->4.0 mm *Safety distance:* 2 cm	**LoE 1a** **Quality Objective:** As often as possible safety distance 2cm in curative radical excision of a melanoma with tumour thickness > 2 mm

MEL 3: Presentation Skin Tumor Board

Numerator: Patients presented in the interdisciplinary skin tumor board **Denominator:** Patients with mucosal melanoma or cutaneous melanoma stage IV	**12.1** Patients with metastatic melanoma (from stage III) shall be presented in an interdisciplinary skin tumour board to coordinate further diagnostics and therapy. The possibility of inclusion in clinical trials shall be examined in every case. **10.8** In the treatment of mucosal melanomas, the specialist disciplines responsible for the respective anatomical region (e.g. maxillofacial surgery, ENT, gynaecology, urology, visceral surgery) shall be involved and participate.	**EC** **Quality Objective:** Presentation of patients with mucosal melanoma or cutaneous melanoma stage IV in interdisciplinary skin tumor board as often as possible

MEL 4: sentinel lymph node biopsy

Numerator: Patients in whom the sentinel lymph node biopsy is performed **Denominator:** Patients with a primary cutaneous melanoma ≥ pT2a and no evidence of locoregional or distant metastasis.	**4.36** For staging, sentinel lymph node biopsy shall be performed from a tumor thickness of 1.0 mm and without evidence of locoregional or distant metastasis.	**LoE 1a** **Quality Objective:** If possible, frequent sentinel lymph node biopsy for primary cutaneous melanoma ≥ pT2a and without evidence of locoregional or distant metastasis

MEL 5: Therapeutic lymphadenectomy

Numerator: Patients with therapeutic LAD for any pT and c/pN1b or c/pN2b or c/pN3b and M0.	**6.19** Therapeutic LAD shall be performed when there is clinical evidence of lymphogenic metastasis (cytologic or histologic	**EC** **Quality Objective:** Therapeutic LAD as often as possible with clinical evidence of lymphogenic

MEL 3: Presentation Skin Tumor Board

Denominator: Patients with malignant melanoma with any pT and c/pN1b or c/pN2b or c/pN3b and M0	confirmation, lymph node ultrasonography, CT, PET/CT) without evidence of distant metastases.	metastasis and no evidence of distant metastases.

MEL 6: Social services counselling

Numerator: Number of patients who received social work counselling **Denominator:** All patients with cutaneous melanoma	**9.1** Patients with malignant melanoma shall be informed about the legal entitlement to a rehabilitation measure. The application procedure shall be initiated in patients with impaired disease processing (then also applies to in situ melanomas), functional or participation disorders already in the context of primary care. Further prerequisites are the existence of rehabilitation capability and a positive rehabilitation prognosis.	**EC** **Quality Objective:** As often as possible counselling by social services for patients with malignant melanoma

MEL 7: First-line therapy cutaneous melanoma stad. IV

Numerator: Number of patients with BRAF inhibitor + MEK inhibitor therapy or anti-PD-1-based first-line therapy **Denominator:** All patients with stage IV cutaneous melanoma with initiated first-line systemic therapy.	**7.12** In the case of BRAF V600 mutation, therapy with a BRAF inhibitor in combination with a MEK inhibitor or checkpoint inhibitor therapy (PD-1 monotherapy or PD-1+CTLA-4 antibody therapy) shall be used.	**LoE 1b** **Quality Objective:** If possible, BRAF inhibitor + MEK inhibitor therapy or anti-PD-1-based first-line therapy for stage IV cutaneous melanoma

MEL 8: Survey of mutation status (KIT, BRAF and NRAS) in mucosal melanoma

Numerator: Number of patients with elevation of mutation status for KIT, BRAF and NRAS **Denominator:**	**10.4** In case of local inoperability or from the stage of lymph node metastasis onwards, the mutation status of mucosal melanomas for KIT, BRAF and NRAS shall be determined.	**EC** **Quality Objective:** If possible, frequent determination of the mutation status for KIT, BRAF and NRAS in mucosal melanoma cT4 and/or N+.

MEL 3: Presentation Skin Tumor Board

All patients with mucosal melanoma cT4 and/or N+		

MEL 9: LDH determination

Numerator: Patients with LDH determination **Denominator:** Patients with malignant melanoma at stage IV entry	**7.7** LDH shall be determined as part of the current AJCC classification in patients with suspected or proven distant metastases.	**LoE 1b** **Quality Objective:** LDH determination as often as possible in patients with malignant melanoma at stage IV onset

19. Oral cavity carcinoma

(Version 3.0, January 2021)

Quality indicator	Reference Recommendation	Evidence base/ further information
OCC 1: R0 situation after curative surgery*		
Numerator: Number of patients with R0 as a result of surgical therapy **Denominator:** All patients with first diagnosis of oral cavity carcinoma and resection with curative intention	Based on the international QI "Surgical margins" (Scotland Health Indicators (ISD)). Corresponds to the goal of the guideline: "In all patients operated on with curative intention, an R0 situation shall be achieved as a result of the surgical therapy".	Not a recommendation, but derived from a specific guideline objective. Quality Objective: As often as possible R0 status after completion of curative intended surgical therapy
OCC 2: Imaging to exclude metastasis		
Numerator: Number of patients with examination of the region from the skull base to the upper thoracic aperture with CT or MRI to determine the N category **Denominator:** All patients with oral cavity carcinoma	No. 6.10 To determine the N category, the entire region from the skull base to the upper thoracic aperture shall be examined with CT or MRI.	**LoE 2+** **Quality Objective:** Imaging as frequently as possible to determine the N category in oral cavity carcinoma.
OCC 3: Imaging to exclude synchronous second tumors, distant metastases, unknown primary tumors (CUP) and recurrences		
Numerator: Number of patients with chest CT to exclude pulmonary tumor involvement (filia, second carcinoma) **Denominator:** All patients with oral cavity carcinoma stage III + IV	No. 21 In patients with advanced oral cavity carcinoma (stage III, IV), a chest CT shall be performed to exclude pulmonary tumor involvement (filia, second carcinoma).	**LoE 3** **Quality Objective:** Imaging as frequently as possible to exclude metastasis in patients with advanced oral cavity carcinoma
OCC 4: Report of findings after resection		
Numerator:	No. 7.4	**LoE 2++**

Number of patients for whom the histopathological findings are documented as follows: tumour location, macroscopic tumour size, histological tumour type according to WHO, histological tumour grade, depth of invasion, lymph vessel invasion, blood vessel invasion and perineural invasion, locally infiltrated structures, classification pT, details of affected areas and infiltrated structures, R-status, extracapsular growth LK Y/N, pN-classification, minimum safety distance in mm. **Denominator:** All patients with initial diagnosis of oral cavity carcinoma and surgery	The histopathological report shall describe, in communication with the clinician, the exact location of any R+ situation that may be present. The tumour preparation shall be sent to the pathologist with clear designation of the anatomical topography. Thread or color marking may be done for this purpose. The histopathologic findings shall include: Tumor location, macroscopic tumor size, histological tumor type according to WHO, histological tumor grade, depth of invasion, lymphatic vessel invasion, blood vessel invasion and perineural invasion, locally infiltrated structures, classification pT, indications of affected districts and infiltrated structures, R status.	**Quality Objective:** Complete report of findings after resection as often as possible

OCC 5: Presentation tumor board

Numerator: Number of patients with interdisciplinary treatment after coordination in tumour boards involving the specialist disciplines of oral and maxillofacial surgery, otorhinolaryngology, radiotherapy, oncology, pathology and radiology **Denominator:** All patients with oral cavity carcinoma	8.1 The treatment of oral cavity carcinoma shall be carried out in an interdisciplinary manner after coordination of each individual case within tumour boards involving the specialist disciplines of oral and maxillofacial surgery, otorhinolaryngology, radiotherapy, oncology, pathology and radiology.	**EC** **Quality Objective:** Presentation in the tumor board as often as possible

OCC 6: cervical lymph node resection*

Numerator: Number of patients with elective neck dissection **Denominator:** All patients with initial diagnosis of oral cavity carcinoma and cN0 of any T category.	8.11 Patients with clinically unremarkable lymph node status (cN0) shall undergo elective neck dissection regardless of T stage.	**LoE 3** **Quality Objective:** Elective neck dissection as often as possible for clinically inconspicuous lymph nodes

OCC 7: Interruption of radiotherapy

Numerator: Number of patients without interruption of radiotherapy **Denominator:** All patients with initial diagnosis of oral cavity carcinoma and radiotherapy	8.27 Interruption of radiotherapy leads to deterioration of tumor control and shall be avoided.	**LoE 2+** **Quality Objective:** No interruption of radiotherapy for oral cavity carcinoma as often as possible
Supplementary notes: Definition of "interruption": an interruption exists if it delays the recommended time to completion of 11 weeks		

OCC 8: Postoperative radio(chemo)therapy

Numerator: Number of patients with postoperative radio- or radiochemotherapy **Denominator:** All patients with initial diagnosis of oral cavity carcinoma T3/T4 category, scarce or positive resection margins, perineural or vascular invasion or LK+.	**8.35** Postoperative radio- or radiochemotherapy shall be given in cases of advanced T stage (T3/T4), scarce or positive resection margins, perineural invasion, vascular invasion and/or lymph node metastases.	**LoE 1++** **Quality Objective:** Postoperative radio- or radiochemotherapy as often as possible for T3/T4 category, scarce or positive resection margins, perineural or vascular invasion or LK+.
Supplementary notes: Definition of "close" safety distance: 1-3 mm		

OCC 9: Dental examination prior to radio(chemo)therapy

Numerator: Number of patients with dental examination before the start of radio- or radiochemotherapy **Denominator:** All patients with oral cavity carcinoma and radio- or radiochemo-therapy	8.42 Patients shall receive a dental examination and, if necessary, conservative and/or surgical dental rehabilitation before undergoing radio/radiochemotherapy in the oral cavity to prevent osteoradionecrosis.	**EC** **Quality Objective:** Dental examination as often as possible before the start of radio(chemo)therapy for oral cavity carcinoma

OCC 10: Psychosocial counselling

Numerator: Number of patients with documented offer of psychosocial care by a social worker	9.8 Patients with oral cavity carcinoma shall be offered psychosocial care by social workers.	**EC** **Quality Objective:** Offer psychosocial care for oral cavity carcinoma as often as possible

Denominator: All patients with oral cavity carcinoma		

*** Indicator can be documented with the updated uniform basic oncology data set and the associated modules (as of: January 2021)**

20. Renal Cell Carcinoma

(Version 2.0, August 2020)

Quality indicator	Reference Recommendation	Evidence base/ further information
NCa 1: Biopsy before ablative therapy		
Numerator: Number of patients with confirmation of diagnosis by punch cylinder biopsy before ablative therapy (RFA or cryoablation). **Denominator:** All patients with initial diagnosis of renal cell Ca and ablative therapy (RFA o. cryoablation).	**4.4** A biopsy shall be performed before ablative therapy.	**EC** **Quality Objective:** If possible, confirm the diagnosis with a punch biopsy before ablative therapy.
NCa 2: Biopsy before systemic therapy		
Numerator: Number of patients with histology before systemic therapy **Denominator:** All patients with renal cell Ca and systemic therapy.	**4.6** If histopathological confirmation of renal cell carcinoma and subtype has not yet been obtained, a biopsy from the primary or a metastasis shall be performed prior to systemic therapy.	**EC** **Quality Objective:** If possible, frequently confirm diagnosis with histology before systemic therapy.
NCa 3: Histological type according to current WHO classification		
Numerator: Number of patients with reports with: - Classification according to WHO u. - Vancouver Classification u. - Staging according to TNM **Denominator:** All patients with renal cell Ca and histology.	**4.9** The histological type of renal cell carcinoma shall be determined according to the current WHO classification. Additional tumor types recommended in the Vancouver Classification of Renal Cell Carcinoma of the International Society of Urologic Pathology (ISUP) shall be diagnosed. In particular, this concerns the following new categories of epithelial tumors: - Tubulocystic renal cell carcinoma - Renal cell carcinoma associated with acquired cystic kidney disease - Clear cell papillary renal cell carcinoma - Translocation-associated renal cell carcinoma - Renal cell carcinoma associated with hereditary leiomyomatosis.	**EC** **Quality Objective:** Reports of findings with the listed information as frequently as possible. **Notes:** Vancouver classification: G. Kristiansen, B. Delahunt, J.R. Srigley et al. Vancouver classification of renal tumors. Recommendations of the 2012 International Society of Uropathology (ISUP) consensus conference. pathologist 2014. doi 10.1007/s00292-014-2030-z.

Quality indicator	Reference Recommendation	Evidence base/ further information
		- WHO classification: 2004 TNM 7th edition

NCa 4: Tumor grade according to Fuhrman

Numerator: Number of patients with indication of tumor grade according to Fuhrman in the diagnostic report. **Denominator:** All patients with clear cell or papillary renal cell Ca.	**4.10** The current recommendations of the TNM classification shall be applied. The tumour grade shall be given for clear cell and papillary renal cell carcinomas according to WHO-ISUP grading. In addition, the percentage of tumor necrosis shall be indicated.	**EC** **Quality Objective:** If possible, indication of tumor grade according to Fuhrman for clear cell or papillary renal cell carcinoma. **Notes**: WHO-ISUP grading

NCa 5: R0 resection

Numerator: Number of patients with R0 resection **Denominator:** All patients with initial diagnosis of renal cell Ca and surgical resection.	**6.10** R0 resection shall be performed for renal tumor removal.	**LoE 3** **Quality Objective:** R0 resection as often as possible.

NCa 6: Nephrectomy for pT1

Numerator: Number of patients with nephrectomy **Denominator:** All patients with initial diagnosis of renal cell Ca pT1.	**6.15** Locally limited tumors in clinical stage T1 shall be operated on in a kidney-preserving manner.	**LoE 3** **Quality Objective: low** Nephrectomy for pT1 as rarely as possible.

NCa 7: Dental examination before bisphosphonate/denosumab therapy

Numerator: Number of patients with a dental examination before the start of therapy **Denominator:** All patients with renal cell carcinoma and bisphosphonate or denosumab therapy	**11.3** To prevent osteonecrosis of the jaw, a dental examination and possible dental rehabilitation as well as instruction in oral hygiene shall be performed before starting drug therapy with bisphosphonates or denusomab.	**LoE 3+** **Quality Objective:** Dental examination as often as possible before starting therapy with bisphosphonate or denosumab

Quality indicator	Reference Recommendation	Evidence base/ further information
NCa 8: Two-year survival metastatic renal cell carcinoma		
Numerator: Number of living patients in the year before the year of recording **Denominator:** All patients with initial diagnosis of metastatic renal cell Ca 3 years prior to year of ascertainment.	**2 Year Survival Metastatic Kidney Cancer** Z: Number of patients with metastatic cancer at diagnosis for whom at least 2 years have elapsed since diagnosis who are alive 2 years after diagnosis N: Number of patients with metastatic cancer at diagnosis for whom at least 2 years have elapsed since diagnosis	**Quality Objective: >=50%** Notes: Source: NHS (UK) http://www.londoncancer.org/media/61502/quality-performance-indicators-010813.pdf (as of 29/06/2015).
NCa 9: 30-day mortality after intervention		
Numerator: Number of patients who died within 30 days post-intervention. **Denominator:** All patients with initial diagnosis of renal cell Ca with renal (partial) resection or ablative therapy (RFA, cryotherapy) as initial therapy.	**30 Day Mortality After Surgery or Ablation** Exclusions: Emergency surgery (nephrectomy). Please Note: This QPI will be reported by treatment type as opposed to a single figure for all treatment options covered by the indicator (i.e. RFA, cryotherapy, SACT or surgery). Z: Number of patients who undergo minimally invasive or operative treatment as first treatment who die within 30 days N: All patients who undergo minimally invasive (RFA, cryotherapy, SACT) or surgical treatment as first treatment for RCC. Target: < 5% (This target reflects the fact that death from any cause, rather than death from renal cancer is being measured by this indicator).	**Quality Objective: <5%** Notes: Source: Scottish Cancer Taskforce. Renal Cancer Clinical Quality Performance Indicators. Published: January 2012.Updated: December 2014 (v2.1)Published by: Healthcare Improvement http://www.healthcareimprovementscotland.org/his/idoc.ashx?docid=211c7043-6d86-4417-acee-3296e0bfb7bd&version=-1 (As at: 29/06/2015).

21. Esophageal Cancer

(Version 2.0, December 2018)

Quality indicator	Reference Recommendation	evidence base/ further information
ECa 1: Complete histopathological evaluation of biopsy material (Suggestion of recording for 1 year in DKG-certified visceral oncology centers, then review of further requirement) Note: "goblet cell-containing Barrett's mucosa" is not recorded in the ADT dataset.		
Numerator: Number of patients with indication of type of neoplastic lesion (Low Grade Dysplasia/Low Grade Intra Epithelial Neoplasia, High Grade Dysplasia/High Grade Intraepithelial Neoplasia=C15x +8077/0, 8077/2., C16x, +8148/0, 8148/2, Tis classification according to UICC, invasive carcinoma), WHO-hist. Type , for invasive carcinoma grading according to current WHO classification, indication whether biopsy from distal esophagus (C 15.5) with Barrett's mucosa containing goblet cells. **Denominator**: All patients with V.a. neoplasia of the esophagus (D.00.1, C.15x., C16x) and biopsy (1.440.9 and 1.440.a)	**6.19** The histopathological report on the biopsy material shall include the following information: • Type of neoplastic lesion (LGD/LG-IEN, HGD/HG-IEN, carcinoma), in particular whether an invasive carcinoma is present (for HGD/HG-IEN: classification on the biopsy as Tis according to UICC) • Histological type according to WHO (in particular distinction between squamous cell versus adenocarcinoma) For invasive adenocarcinomas: • Degree of differentiation (grading) according to current WHO classification • For lesions in the distal esophagus: is a goblet cell-containing Barrett's	**EC**

Quality indicator	Reference Recommendation	evidence base/ further information
ECa 2: Complete histopathological findings of local excidates		
Numerator: Number of patients with indication of type of neoplastic lesion (C15x +8077/0, 8077/2., C16x, +8148/0, 8148/2), WHO class, grading, lymphatic and/or venous invasion, depth (depth of invasion) + indication of circular and basal resection margin. **Denominator:** All patients with neoplasia of the esophagus (D.00.1, C.15x, C16x) and endoscopic resection (5.422.2, 5.422.0, 5.422.2,5.422.3)	**6.21.** Histopathological findings on local excisional data (endoscopic resection; ER) shall include the following: Size of the neoplastic lesion in 3 dimensions, if possible Type of neoplastic lesion (LGD/LG-IEN, HGD/HG-IEN, carcinoma) - in particular, whether an invasive carcinoma is present (in the case of HGD/HG-IEN: classification on the resectate as pTis according to UICC) If carcinoma is detected: histological type according to WHO (in particular differentiation squamous cell versus adenocarcinoma, other rare types) For invasive adenocarcinomas: differentiation grade (grading) according to current WHO classification Maximum depth of infiltration: pT1a (m1, m2, m3, m4) / pT1b (sm1, sm2, sm3) plus infiltration depth in µm (or higher pT category). Lymphatic vessel and/or vein invasion (L0 vs. L1, V0 vs. V1) Summary assessment of the risk of LK metastasis: low-risk vs. high-risk resection margins with regard to the neoplasia (for ER in toto circular and basal RR; for "piecemeal" ER basal RR, since here the circular RR must usually be evaluated histo-pathologically as RX)	**EC**

Quality indicator	Reference Recommendation	evidence base/ further information
Note: For the collection of this indicator, data fields for the indication of the circular and basal resection margin and depth of invasion shall be included in the specific module of the general basic data set of the ADT. Size in three dimensions and summary assessment of LK metastatic risk are not documentable		

Quality indicator	Reference Recommendation	evidence base/ further information
ECa 3: Complete histopathological findings of the surgical resectate		
Numerator: Number of patients with indication of size of neoplastic lesion, type of lesion (C15x +8077/0, 8077/2., C16x, +8148/0, 8148/2, Tis), WHO class. Grading, pT, pN, Ratio LK, L, V, R-Status (TNM) **Denominator:** All patients with neoplasia of the esophagus and surgical resection (D.00.1, C.15x, C16x) and surgical resection (OPS 5.422.0, all 5.423, 5.424, 5.425, 5.426)	**6.22.** Histopathological findings on surgical resected specimens shall include the following: Size of the neoplastic lesion Location of the tumour centre in relation to the ÖGJ and indication whether the tumour crosses the ÖGJ Type of neoplastic lesion (LGD/LG-IEN, HGD/HG-IEN, carcinoma) - in particular, whether an invasive carcinoma is present (for HGD/HG-IEN: classification as pTis according to UICC) In case of carcinoma detection: Histological type according to WHO (especially differentiation squamous cell vs. adenocarcinoma, other rare types) -Differentiation grade (grading) -Maximum depth of infiltration (pT)-Lymph or hemangio invasion : L0 vs. L1, V0 vs. V1)-Resection margins (oral, aboral and circumferential): R0 / R1-Lymph node status according to UICC (pN) and ratio of number of affected and examined lymph nodes (.../...LK)	**EC**

Quality indicator	Reference Recommendation	evidence base/ further information
Note: **The localization of the tumor center in relation to the esophago-gastric junction (ÖGJ) and whether the tumor crosses the ÖGJ cannot be documented.**		

ECa 4: Therapy recommendation from interdisciplinary tumor conference

Numerator: Number of patients with therapy recommendation from interdisciplinary tumor conference before therapy (staging completed) **Denominator:** All patients with neoplasia of the esophagus (D.00.1, C.15x, C16x)	**8.1.** 1. therapy recommendations shall be made in an interdisciplinary tumor conference. 2 Staging information, patient comorbidities, nutritional status, and patient preference shall be considered as the basis for treatment recommendation.	**EC**
Note: **Only the first part of the recommendation was assessed as operationalizable. The guideline authors advocated that the participants of the tumor conference be determined by the DKG Certification Commission for Visceral Oncology Centers. The primary case shall be recorded**		

ECa 5: Complete endoscopic resection of an intraepithelial neoplasia or a mucosal early carcinoma in Barrett's esophagus

Numerator: Number of patients with R0 **Denominator:** All patients with a diagnosis of high-grade intraepithelial neoplasia (C16x, 8148/2) or mucosal carcinoma (=8140/3) L0, V0, G1/G2, no ulceration, depth of infiltration ≤ m3 in Barrett's esophagus (K22.7) and endoscopic resection (5.422.2, 5.422.20. 5.422.3, 5.422.4).	**8.2.** a. If high-grade intraepithelial neoplasia or mucosal carcinoma (L0, V0, no ulceration, grading G1/G2, depth of infiltration ≤ m3) is detected in Barrett's esophagus, endoscopic resection shall be performed, as this provides staging of the lesion with the question of depth of infiltration in addition to therapy. Therefore, an endoscopic complete resection with curative intention shall be aimed for. After successful resection of neoplasms in Barrett's esophagus, the non-neoplastic Barrett's mucosa shall be thermally ablated to decrease the rate of metachronous neoplasms.	**EC**
Note: **Only parts a+b of the recommendation were implemented. "no ulcerations" not mapped in documentation systems**		

ECa 6: Complete surgical resection

Numerator: Number of patients with R0 **Denominator:** All patients with neoplasia of the esophagus (D.00.1, C.15x, C16x) and surgery (surgical resection OPS 5.422.0, all 5.423, 5.424, 5.425, 5.426)	**8.9.** The goal of surgical resection for squamous cell carcinoma and adenocarcinoma is complete removal of the tumor (oral, aboral, and circumferential) and regional lymph nodes.	**EC**

ECa 7: preoperative radiotherapy in patients with squamous cell carcinoma of the esophagus T3/T4

Numerator: Number of patients with preoperative radiochemotherapy **Denominator:** All patients with squamous cell carcinoma of the esophagus (C15x) and cT3/cT4	**8.27.** Preoperative radiochemotherapy followed by complete resection shall be performed in operable patients with cT3 **squamous cell carcinoma of** the esophagus and resectable cT4 tumors.	**LoE 1a**
Note: Only the first part of the recommendation has been implemented.		

ECa 8: perioperative chemotherapy or preoperative radiochemotherapy in operable patients with adenocarcinoma of the esophagus.

Numerator: Number of patients with pre- and postoperative chemotherapy or preoperative radiochemotherapy **Denominator:** All patients with adenocarcinoma of the esophagus (C.16x, 8140/3) and surgery (OPS 5.422.0, all 5.423, 5.424, 5.425, 5.426) and cT3 or cT4	**8.24.** In operable patients with adenocarcinoma of the esophagus or esophagogastric junction category cT3 and resectable cT4 tumors, perioperative chemotherapy or preoperative radiochemotherapy shall be given.	**LoE 1a** Literature: [3-8]

ECa 9: System therapy of metastatic esophageal carcinoma

Numerator: Number of patients with systemic chemotherapy (first line) **Denominator:** All patients with metastatic adenocarcinoma of the esophagus (C16.x, 8140/3,M1)	**9.1.** Patients with metastatic or locally advanced adenocarcinoma of the esophagus that cannot be treated curatively shall be offered systemic chemotherapy. The therapeutic goal is to prolong survival and maintain quality of life.	**LoE 1a**

ECa 10: Anastomotic insufficiency after surgical resection

Numerator: Number of patients with anastomotic insufficiency (ICD: K91.83 "Insufficiencies of anastomoses and sutures after surgery on: Anus, intestine, stomach, esophagus, rectum) treated endoscopically, interventional or surgically **Denominator:** All patients with neoplasia of the esophagus (D.00.1, C.15x, C16x) and surgery (surgical resection OPS 5.422.0, all 5.423, 5.424, 5.425, 5.426)	Outcome indicator based on a corresponding QI from Belgium: "OC9: Proportion of patients experiencing anastomotic leakage after oesophagectomy". Classification of anastomotic insufficiency in I-III. I= locally defect, no change in therapy, only medicaments or diet modification II: Localized defect requiring intervention, but no surgery, e.g. IR drain, stent or bedside opening III: Localized defect requiring surgical therapy -shall be recorded	Definition as in Low et al, International Consensus on Standardization of Data Collection for Complications Associated With Esophagectomy: Esophagectomy Complications Consensus Group (ECCG). , 2015 [9]

ECa 11: 11.1 and 11.2: Mortality after surgery

Counter 11.1: Number of patients who died postoperatively after 30 days	Outcome indicator based on a corresponding QI from Belgium: OC6: Esophageal resection mortality rate within 30 days [10]	Mortality Rate: 90 days better than 30 days to measure.

Counter 11.2: Number of patients who died postoperatively after 90 days **Denominator 11. 1+11.2:** All patients with neoplasia of the esophagus (D.00.1, C.15x, C16x) and surgery (surgical resection OPS 5.422.0, all 5.423, 5.424, 5.425, 5.426)		

22. Ovarian tumors

(Version 4.0. March 2020)

Quality indicator	Reference Recommendation	Evidence base/ further information
OvCa 1: Operative staging of early ovarian cancer		
Numerator: Number of patients with surgical staging with: • Laparotomy • Peritoneal Cytology • Peritoneal biopsies • bilateral adnexal extirpation • Hysterectomy, extraperitoneal procedure if necessary • Omentectomy at least infracolic • bds. pelvic and paraaortic lymphonodectomy **Denominator:** All patients with initial diagnosis of ovarian cancer FIGO I-IIIA	**7.1** Optimal staging shall include the following surgical steps: • Longitudinal laparotomy • Inspection and palpation of the entire abdominal cavity • Peritoneal Cytology • Biopsies from all abnormal sites • Peritoneal biopsies from inconspicuous regions • bilateral adnexal extirpation • Hysterectomy, extraperitoneal procedure if necessary • Omentectomy at least infracolic • Appendectomy (for mucinous/unclear tumor type) • bds. pelvic and para-aortic lymphonodectomy	**EC** **Quality Objective:** Surgical staging as often as possible for ovarian cancer FIGO I - IIIA
OvCa 2: Offer for genetic testing		
Numerator: Number of patients with offer of genetic testing **Denominator:** All patients with first diagnosis of ovarian cancer	**5.1** Patients diagnosed with ovarian cancer shall be informed about the risk of hereditary disease and offered genetic testing.	**LoE 2+** **Quality Objective:** Offer of genetic testing as often as possible
OvCa 3: Macroscopically complete resection of advanced ovarian cancer*.		
Numerator: Number of patients with macroscopically complete resection **Denominator:** All patients with initial diagnosis of ovarian cancer ≥ FIGO IIB and surgical tumor removal without prior chemotherapy.	**7.6** The goal of primary surgery for advanced ovarian cancer shall be a macroscopically complete resection.	**EC** **Quality Objective:** Macroscopically complete resection as often as possible

Quality indicator	Reference Recommendation	Evidence base/ further information
OvCa 4: Surgery advanced ovarian cancer by gynecooncologist		
Numerator: Number of patients whose definitive surgical therapy was carried out by a gynaecological oncologist **Denominator:** All patients with initial diagnosis of ovarian cancer FIGO ≥IIB after completion of surgical therapy.	**7.8** In the event of an unexpected diagnosis of advanced ovarian cancer, histological confirmation and description of the spread shall be performed. Definitive treatment shall then be carried out by a gynaecological oncologist in an appropriate facility.	**LoE 4** **Quality Objective:** Surgical therapy by gynaecological oncologists as often as possible
OvCa QI 5: Postoperative chemotherapy advanced ovarian cancer*.		
Numerator: Number of patients with postoperative chemotherapy **Denominator:** All patients with initial diagnosis of ovarian cancer ≥ FIGO IIB and chemotherapy.	**7.10** The treatment sequence shall be primary surgery followed by chemotherapy.	**LoE 1+** **Quality Objective:** As often as possible postoperative Chemotherapy for advanced ovarian cancer and chemotherapy
OvCa 6: No adjuvant chemotherapy early ovarian cancer		
Numerator: Number of patients with adjuvant chemotherapy **Denominator:** All patients with initial diagnosis of ovarian carcinoma FIGO IA, G 1 and complete surgical staging.	**8.1** Patients with stage IA grade 1 ovarian cancer after complete surgical staging shall not receive adjuvant chemotherapy.	**LoE 1+** **Quality Objective:** As often as possible, no adjuvant chemotherapy in FIGO IA, G1 and complete surgical staging.
OvCa 7: Platinum-containing chemotherapy early ovarian cancer*.		
Numerator: Number of patients with platinum-containing chemotherapy	**8.2** Patients with stage IC or IA/B and grade 3 ovarian cancer shall receive	**LoE 1+** **Quality Objective:** As often as possible platinum-containing

Quality indicator	Reference Recommendation	Evidence base/ further information
Denominator: All patients with initial diagnosis OC FIGO IC or IA/B with grade 3	platinum-containing chemotherapy for 6 cycles.	Chemotherapy for initial diagnosis of ovarian cancer FIGO IC or IA/B with grade 3

OvCa 8: First-line chemotherapy for advanced ovarian cancer

Numerator: Number of patients with 6 cycles of first-line chemotherapy Carboplatin AUC 5 and Paclitaxel 175mg/m2 **Denominator:** All patients with initial diagnosis of ovarian cancer ≥ FIGO IIB	**8.5** First-line chemotherapy for patients with advanced ovarian cancer (IIb-IV) shall consist of carboplatin AUC 5 and paclitaxel 175 mg/m2 over 3 h i.v. for a total of 6 cycles every 3 weeks.	**LoE 1++** **Quality Objective:** If possible, frequently 6 cycles of first-line chemotherapy carboplatin AUC 5 u. paclitaxel 175mg/m2 for initial diagnosis of ovarian cancer ≥ FIGO IIB.

OvCa 9: Combination therapy for platinum-sensitive relapse

Numerator: Number of patients with platinum-containing combination therapy **Denominator:** All patients with platinum-sensitive recurrence of ovarian cancer and recurrence chemotherapy, outside of clinical trials.	**9.6** Patients with platinum-sensitive ovarian cancer recurrence shall receive platinum-containing combination therapy when chemotherapy is indicated. The following combinations may be considered[a]: • Carboplatin / Gemcitabine • Carboplatin / Gemcitabine / Bevacizumab[b] • carboplatin / paclitaxel • Carboplatin / Paclitaxel / Bevacizumab[b] • Carboplatin / pegylated liposomal doxorubicin a: alphabetical order b: in patients with first relapse and without prior VEGF directed therapy	**EC** **Quality Objective:** If possible, platinum-containing combination therapy for platinum-sensitive recurrence and recurrence chemotherapy, outside of clinical trials

OvCa 10: No adjuvant therapy BOT*

Numerator: Number of patients with adjuvant therapy	**11.7** Patients with borderline tumors shall not receive adjuvant therapy.	**LoE 1+** **Quality Objective:**

Quality indicator	Reference Recommendation	Evidence base/ further information
Denominator: All patients with initial diagnosis of borderline tumor		No adjuvant therapy for borderline tumor

* Indicator can be documented using the updated uniform basic oncology dataset and associated modules (as of January 2019).

23. Palliative care

(Version 2.2, September 2020)

Quality indicator	Reference Recommendation	Evidence base/ further information
PAL 1: Reduction of respiratory distress		
Numerator: Number of patients with reduction of breathlessness within 48h **Denominator**: All patients diagnosed with "non-curable cancer" (APV and SPV) with moderate/severe respiratory distress on hospital admission.	8.3 Repeated assessment of dyspnea before, during and after symptomatic therapy shall be part of the assessment. Guideline Objectives: Improvement of symptom control; to this end, common symptoms and problems shall be treated according to the current state of science and clinical expertise (chapters on respiratory distress, tumour pain, fatigue, sleep-related disorders/nocturnal restlessness, nausea and vomiting (not tumour therapy-induced), constipation, malignant intestinal obstruction (MIO), malignant wounds, anxiety and depression)	**EC** **Quality Objective:** Reduction of respiratory distress as often as possible within 48 h after hospital admission in patients with the diagnosis "non-curable cancer". Screening instruments (open list of validated instruments): Modified Borg Visual analogue scale Numeric Rating Scale MIDOS, IPOS (HOPE/National Palliative Register)
PAL 2: Pain reduction		
Numerator: Number of patients with reduction of pain within 48 h **Denominator**: All patients diagnosed with "non-curable cancer" (APV and SPV) with moderate/severe pain on hospital admission.	9.1 Pain history and pain-related clinical examination shall be part of every pain diagnosis. Objectives of the guideline: Improvement of symptom control; to this end, common symptoms and problems are to be treated according to the current state of science and clinical expertise (chapters on respiratory distress, tumour pain, fatigue, sleep-related disorders/nocturnal restlessness, nausea and vomiting (not tumour therapy-induced), constipation,	**EC** **Quality Objective:** Reduction of pain as often as possible within 48 hours after hospital admission in patients with a diagnosis of "non-curable cancer". Screening instruments (open list of validated instruments): McGill Pain Questionnaire Verbal Rating Scale Numeric Rating Scale MIDOS, IPOS (HOPE/National Palliative Register) if neuropathic pain is suspected, also: painDETECT or DN4

Quality indicator	Reference Recommendation	Evidence base/ further information
	malignant intestinal obstruction (MIO), malignant wounds, anxiety and depression).	
PAL 3: Opioids and laxatives		
Numerator: Number of patients without therapy with osmotically active and/or stimulating laxatives **Denominator**: All patients diagnosed with "non-curable cancer" (APV and SPV) with opioid medication outside the dying phase (= 7 days before death)	Pain 9.25 Laxatives for the treatment or prevention of opioid-induced constipation shall be routinely prescribed. 13.6 In drug mono- or combination therapy for the treatment of constipation, osmotically active and/or stimulating laxatives shall be used.	**LoE 1+** **Quality Objective:** Use of laxatives as frequently as possible in patients with a diagnosis of non-curable cancer and opioid medication
PAL 4: Symptom assessment in the dying phase		
Numerator: Number of patients with symptom assessment by means of a validated screening instrument in the last 72 h before death **Denominator**: All deceased patients (APV and SPV)	19.25 Anxiety occurring during the dying phase shall be evaluated regularly. In addition to verbal expressions, attention shall be paid to clinical signs such as agitation, sweating, facial expressions or defensive reactions.	**EC** **Quality Objective:** Symptom assessment as often as possible during the dying phase Screening instruments (open list of validated instruments: IPOS MIDOS (HOPE/National Palliative Register)
PAL 5: Recording of agitation in the dying phase		
Numerator: Number of patients with evaluation of agitation in the last 72 h before death **Denominator:** All deceased patients (APV and SPV)	19.26 In the case of agitation in the dying phase, the primary triggering causes shall be determined, e.g. pain, constipation, urinary retention, respiratory distress, anxiety and/or delirium.	**EC** **Quality Objective:** Assessment of agitation in the dying phase as often as possible Screening instruments: Will have to be recorded via IPOS and MIDOS in future

Quality indicator	Reference Recommendation	Evidence base/ further information
PAL 6: Termination of tumour-specific measures in the dying phase*.		
Numerator: Number of patients with tumor-specific measures (systemic therapy, radiotherapy) within 14 days before death **Denominator**: All deceased patients (APV and SPV)	19.32 Tumor-specific drugs and measures shall be stopped in the dying phase.	**LoE 1+** **Quality Objective:** Termination of tumour-specific measures in the dying phase as often as possible
PAL 7: Oral care		
Numerator: Number of patients with oral care **Denominator**: All patients diagnosed with "non-curable cancer" (APV and SPV) and dry mouth (ICD-10-GM R 68.2)	14.12 To alleviate dry mouth in patients with non-curable cancer and MIO, oral care including lip moisturization shall be offered and performed regularly and several times a day.	**EC** **Quality Objective:** Oral care as often as possible for patients with non-curable cancer
PAL 8: Assessment of malignant wounds		
Numerator: Number of patients with assessment of the exulcerating tumor by means of a specific assessment instrument according to the guideline **Denominator**: All patients diagnosed with "non-curable cancer" (APV and SPV) and exulcerating tumor.	15.2 The assessment of the malignant wound with a complete analysis of the wound situation shall be carried out in writing using structured wound documentation forms at the start of care and for further monitoring at regular intervals during the course of care.	**EC** **Quality Objective:** Assessment of malignant wounds as frequently as possible in patients with incurable cancer and exulcerating tumour Specific assessment tools: HOPE FKB-20 FLQA-wk Wound-QoL Pain assessment in patients with chronic wounds

Quality indicator	Reference Recommendation	Evidence base/ further information
PAL 9: Documentation of therapy goals		
Numerator: Number of patients with documented treatment goals at the time of diagnosis of "non-curable cancer **Denominator**: All patients diagnosed with "non-curable cancer" (APV and SPV)	7.7 Therapy goals in the treatment of patients with a non-curable cancer shall be reviewed regularly and adapted to the changed disease and treatment situation or the changed wishes, values and goals of the patient.	**EC** **Quality Objective:** Documentation of treatment goals as frequently as possible for patients with non-curable cancer
PAL 10: Symptom recording using MIDOS or IPOS [2]		
Numerator: Number of patients with symptom recording using MIDOS or IPOS **Denominator**: All patients diagnosed with "non-curable cancer" (APV and SPV)	5.5 In the case of a non-curable cancer, the physical, psychological, social and spiritual needs as well as the stresses and information needs of patients and relatives shall be recorded repeatedly and when the clinical situation changes.	**EC** **Quality Objective:** As frequent as possible symptom recording using MIDOS/IPOS in patients with non-curable cancer
PAL 11: Specialised palliative care		
Numerator: Number of patients who received specialized palliative care (inpatient: palliative ward, palliative service, palliative medical day clinic, inpatient hospice; outpatient: SAPV, specialized palliative outpatient clinic) received **Denominator:** All patients who have died of a tumor disease	International search for quality indicators: QI: Specialized palliative care **Numerator:** number of people who died with cancer who received specialized palliative care (hospital palliative unit OR palliative daycare centre OR multidisciplinary home care) in the last 2 years prior to death **Denominator:** number of people who died with cancer [11]	**EC** **Quality Objective:** Evaluation of the care situation of cancer patients with regard to specialised palliative care

* Indicator can be documented using the updated uniform basic oncology dataset and associated modules (as of January 2019).

[2] The DEGAM is in favour of quality indicator 10 not applying to GPs, as there is no reliable evidence of the benefit of such a procedure on patient-relevant outcomes at this level of care.

24. Pancreatic Cancer

(Version 1.0, October 2013)

Quality indicator	Underlying recommendation/statement	Evidence base/further comments
PanCa 1: R0 resection		
Numerator: Number of patients with first diagnosis of pancreatic cancer with R0 resection **Denominator:** All patients with initial diagnosis of pancreatic cancer and resection	**6.5** The goal of resection in pancreatic cancer shall be resection in healthy tissue (R0).	**Quality Objective** R0 resection as often as possible Target value: 70 **Evidence base** LoE 1a Note R0-determination according to recommendation 6.10
PanCa 2: LK removal		
Numerator: Number of patients with initial diagnosis of pancreatic cancer, surgical resection and removal of at least 10 lymph nodes **Denominator:** All patients with initial diagnosis of pancreatic cancer and surgical resection	**6.24:** At least 10 regional lymph nodes shall be removed during resection of pancreatic cancer.	**Quality Objective** In case of resection, removal of at least 10 LK as often as possible Target value: 85 **Evidence base** GCP (expert consensus) Note Resection: pancreatic head resection, left resection, pancreatectomy

Quality indicator	Underlying recommendation/statement	Evidence base/further comments
PanCa 3: Pathology report content		
Numerator: Number of reports of findings with indication of: pT, pN, M Tumor Grading Ratio of affected to removed LK **Denominator:** All diagnostic reports of patients with pancreatic cancer and tumor resection	**6.25** In the case of resection of a pancreatic carcinoma, the ratio of affected to total removed lymph nodes shall be stated in the pathological-diagnostic report. **6.33** The indication of the pT-, pN- and M-category as well as the tumor grading shall be indicated in the pathology report.	**Quality Objective** Complete pathology reports as often as possible **Evidence base** Recommendation 6.25: LoE 2b Recommendation 6.33: LoE 2b Note TNM: see [12]
PanCa 4: Adjuvant chemotherapy		
Numerator: Number of patients with first diagnosis of pancreatic cancer UICC stad. I-III, R0 resection and adjuvant chemotherapy with gemcitabine or 5-FU/folinic acid **Denominator:** All patients with initial diagnosis of pancreatic cancer UICC stad. I-III and R0 resection	**7.1** After R0 resection of UICC stage I-III pancreatic cancer, adjuvant chemotherapy shall be administered. **7.4** The following chemotherapy protocols shall be used adjuvantly: - gemcitabine - 5-FU/folinic acid (Mayo protocol)	**Quality Objective** Adjuvant chemotherapy with gemcitabine and/or 5-FU/folinic acid as often as possible Reference range: 50 **Evidence base** Recommendation 7.1: LoE 1b Recommendation 7.4: LoE 1b Note UICC: [12] Exclusion in the **Denominator**: Patients who die within 60 days postoperatively or refuse chemotherapy
PanCa 5: Palliative chemotherapy		
Numerator: Number of patients with pancreatic cancer UICC stad. III or IV, ECOG 0-2 and palliative chemotherapy **Denominator:** All patients with pancreatic cancer UICC stad. III	**8.1** In metastatic or locally advanced pancreatic cancer, palliative chemotherapy shall be given if the ECOG performance status is 0 to 2.	**Quality Objective** As often as possible palliative chemotherapy stad. III or IV, ECOG 0-2 **Evidence base** LoE 1a Note UICC: [12]

Quality indicator	Underlying recommendation/statement	Evidence base/further comments
(palliative situation) o. IV and ECOG 0-2		Palliative chemotherapy: 8.3 ff.

Abbreviations: LoE = Level of Evidence, EG = Grade of Recommendation, Pancreatic CA = pancreatic cancer, UICC = International Association Against Cancer, ECOG = Eastern Cooperative Oncology Group, QI = quality indicator, stad. = stage, pat. = patient, LK = lymph node.

25. Penis Cancer

(Version 1.0, August 2020)

Quality indicator	Reference Recommendation	Evidence base/ further information
Penis 1: Psychosocial screening		
Numerator: Number of patients screened for psychosocial stress **Denominator**: All patients with penile carcinoma	3.7All patients shall receive screening for psychosocial distress. Psycho-oncological screening shall be performed as early as possible, at appropriate intervals, if clinically indicated, or repeatedly during the course of the disease if there is a change in the patient's disease status (e.g. recurrence or progression of the disease).	**EC** **Note:** Validated screening instruments according to S3 guideline psychooncology Quality objective: Screening for psychosocial stress in penile cancer patients as frequently as possible
Penis 2: Report of findings after surgical resection		
Numerator: Number of patients with the following information in the pathology report: • Histological subtype according to WHO classification • Grading • anatomical localization • TNM classification • perineural invasion • Infiltration depth • lymphovascular invasion • venous invasion • Presence of precursor lesions (yes/no) • Presence of concomitant inflammatory diseases (yes/no) • Association with HPV infections (yes/no) **Denominator**:	4.6 In addition to the histological tumour type and grading of the penile carcinoma, the pathological report on the primary tumour shall contain statements on the following prognostic factors: • anatomical localization, • perineural invasion, • Infiltration depth, • lymphovascular invasion • venous vascular invasion, • Growth patterns on the invasion front.	**EC** If possible, complete pathological report after surgical resection for initial diagnosis of penile carcinoma

Quality indicator	Reference Recommendation	Evidence base/ further information
All patients with initial diagnosis of penile carcinoma (ICD-10: C60) and surgical resection		

Penis 3: Report of findings after surgical removal of lymph nodes

Numerator: Number of patients with the following information in the pathological findings report: Number of lymph nodes (removed/infested) Maximum metastasis size Capsule overgrowth (yes/no) **Denominator**: All patients with initial diagnosis of penile carcinoma (ICD-10: C60) and surgical removal of lymph nodes	4.7 The pathological report of the lymph nodes shall include the number of lymph nodes removed, the number of affected lymph nodes and the maximum metastasis size, as well as statements on whether the metastasis remains confined to the lymph node or exceeds the lymph node capsule.	**EC** **Quality Objective:** If possible, complete pathological report after surgical removal of lymph nodes in the case of initial diagnosis of penile carcinoma

Penis 4: Invasive lymph node diagnostics

Numerator: Number of patients with invasive lymph node diagnostics (modified inguinal lymphadenectomy or sentinel lymph node biopsy) **Denominator**: All patients with initial diagnosis of penile carcinoma ≥ pT1b, cN0	6.5 In penile carcinomas from stage pT1b onwards, clinically inconspicuous, nonpalpable inguinal lymph nodes shall be examined invasively. This can be done by modified inguinal lymphadenectomy or by dynamic sentinel lymph node biopsy.	**LoE 3** **Quality objective:** Invasive lymph node diagnostics as often as possible for the initial diagnosis of penile carcinoma from stage pT1b and cN0 onwards

Penis 5: Control biopsy after topical drug therapy or laser therapy

Numerator: Number of patients with control biopsy **Denominator:** All patients with an initial diagnosis of penile carcinoma and topical drug therapy (5-FU, Imiquimod) or laser therapy.	7.9 After topical drug therapy or laser therapy, a control biopsy shall be performed postintervention to verify local tumor control and regular long-term follow-up shall be performed.	**EC** **Quality Objective:** As frequent as possible control biopsies after topical drug therapy or laser therapy for the initial diagnosis of penile carcinoma

Penis 6: Ipsilateral pelvic lymph node removal

Numerator: Number of patients with ipsilateral pelvic lymph node removal	7.36 Pelvic lymph node removal (iliac lymph node group) shall be performed ipsilaterally in patients with 2 or more affected inguinal	**EC** **Quality Objective:** If possible, frequent ipsilateral pelvic lymph node

Quality indicator	Reference Recommendation	Evidence base/ further information
Denominator: All patients with an initial diagnosis of penile carcinoma (ICD-10: C60), pN3	lymph nodes or for capsular lymph node metastases.	removal for initial diagnosis of penile carcinoma with pN3

Penis 7: Presentation tumor board

Numerator: Number of patients with presentation in the tumor board **Denominator**: All patients with metastatic penile carcinoma, M1	7.43 Patients with metastatic penile carcinoma and/or the need for multimodal therapy shall be discussed in an interdisciplinary tumor board.	**EC** **Quality Objective:** Presentation of patients with metastatic penile carcinoma, M1 in the tumor board as often as possible

Penis 8: Neoadjuvant chemotherapy

Numerator: Number of patients with neoadjuvant chemotherapy **Denominator**: All patients with initial diagnosis of penile carcinoma cN3 (fixed inguinal LK) and ECOG < 2.	7.44 Penile carcinoma patients with fixed inguinal lymph nodes with good general condition (ECOG < 2) shall receive neoadjuvant chemotherapy.	**LoE 3** **Quality Objective:** Neoadjuvant chemotherapy as often as possible for initial diagnosis of penile carcinoma with cN3 (fixed inguinal LK) and ECOG < 2

The **Numerator** is always a subset of the **Denominator**.

26. Prostate Cancer

(Version 5.1, May 2019)

Quality indicator	Reference Recommendation	Evidence base/ further information
PCa 1: Report of findings Punch biopsy*		
Numerator: Number of patients with report of findings with indication of: • Localization and number of carcinoma-positive tissue samples in relation to the number of punctures taken. • Semiquantitative estimation of the percentage of total carcinoma area/total punch area • Gleason grade: all primary and secondary grades as well as the least differentiated grade, each in " %". • Indication of the total Gleason score. **Denominator:** All patients with initial diagnosis of prostate carcinoma and punch biopsy	**4.42** In case of positive carcinoma detection, the following information shall be provided by the pathologist to the urologist: • Number and location of carcinoma-positive tissue samples. • Semiquantitative estimation of the percentage of total carcinoma area/total punch cylinder area. • Gleason grade: Indication of all primary and secondary grades as well as the least differentiated grade, each in "%". Indication of the total Gleason score. • Lymphatic vessel (L) and venous (V) invasion (L0 or L1, V0 or V1). • Perineural infiltration (Pn0 or Pn), if assessable, shall indicate capsular infiltration, capsular overgrowth (cT3a), and seminal vesicle infiltration (cT3b).	**LoE 4** **Quality Objective:** Complete report of findings after punch biopsy as often as possible
PCa 2: Report of findings lymph nodes*		
Numerator: Number of patients with reports of findings indicating: pN category	**4.49** All lymph nodes shall be macroscopically dissected and then embedded, examined and counted to determine the lymph node category.	**LoE 4** **Quality Objective:** Complete reports of findings after lymphadenectomy as often as possible

Quality indicator	Reference Recommendation	Evidence base/ further information
Number of affected LK in relation to removed LK **Denominator:** All patients with initial diagnosis of prostate cancer and lymphadenectomy	The lymph nodes shall be assessed separately according to the regions indicated. After histological examination, the pN category (pN0 or pN1) shall be determined. The total number and the number of affected lymph nodes as well as the diameter of the largest metastasis shall be indicated.	

PCa 3: Active Surveillance*

Numerator: Number of patients with PSA value ≤ 10 ng/ml and Gleason score ≤ 6 and cT1 or cT2a and Tumor in ≤ 2 punches with removal of 10-12 punches, and ≤ 50 % tumor per punch before the start of the AS **Denominator:** All patients with an initial diagnosis of prostate cancer and Active Surveillance	**5.8** a. The following parameters shall be a prerequisite for the selection of an Active Surveillance strategy: -PSA value ≤ 10 ng/ml; -Gleason score ≤ 6; -cT1 or cT2a; -Tumor in ≤ 2 punctures with guideline-guided removal of 10-12 punctures. -≤ 50% tumor per punch. b. In Gleason 3+4 (7a), AS shall be tested in the context of studies. c. Age and comorbidity shall be taken into account when determining the indication.	**LoE 4** **Quality Objective:** If possible, frequent presence of the listed parameters at the start of AS

PCa 4: Radiotherapy and hormone ablative therapy for localized high-risk prostate cancer*

Numerator: Number of patients with additional adjuvant hormone ablative therapy **Denominator:** All patients with initial diagnosis of high risk T1-2 N0	**5.67** a. Patients with localized prostate carcinoma of the high risk profile shall receive adjuvant hormone ablative therapy in addition to percutaneous radiotherapy. This can start up to 6 months before radiotherapy.	**LoE 1+** **Quality Objective:** Adjuvant hormone ablative therapy as often as possible for localized high-risk prostate cancer and percutaneous radiotherapy

Quality indicator	Reference Recommendation	Evidence base/ further information
M0 prostate carcinoma and percutaneous radiotherapy.	b. Hormone ablative therapy shall last at least 24 months, preferably 36 months. c. In patients with localized prostate carcinoma of the high risk profile, the decision on the duration of hormone ablative therapy shall be made individually, in particular depending on comorbidity and tolerability.	
Notes: High risk: PSA > 20 ng/ml or Gleason score = 8 or cT category 2c.		

PCa 5: No hormone ablative therapy for locally advanced prostate cancer with radical prostatectomy*

Numerator: Number of patients with adjuvant hormone ablative therapy **Denominator:** All patients with initial diagnosis of prostate carcinoma T3-4 N0 M0 and RPE	**5.64** a. In patients with clinically locally advanced prostate carcinoma, a prognostic advantage of neoadjuvant hormone ablative therapy has not been proven. b. After radical prostatectomy, patients with locally advanced prostate carcinoma without lymph node metastases (PSA in the zero range) shall not receive adjuvant hormone ablative therapy.	**LoE 1+** **Quality Objective:** No adjuvant hormone ablative therapy in locally advanced prostate cancer and radical prostatectomy (RPE).

PCa 6: No hormone ablative therapy for low-risk localized prostate cancer and percutaneous radiotherapy*

Numerator: Number of patients with hormone ablative therapy **Denominator:** All patients with initial diagnosis of prostate carcinoma T1-2 N0 M0 with low risk and percutaneous radiotherapy.	**5.65** Patients with low-risk localized prostate cancer shall not receive hormone ablative therapy in addition to radiotherapy.	**LoE 1+** **Quality Objective:** No adjuvant hormone ablative therapy for low-risk localized prostate carcinoma and percutaneous radiotherapy.

PCa 7: Salvage radiotherapy for recurrent prostate cancer*

Numerator: Number of patients starting SRT and with PSA<0.5ng/ml **Denominator:** All patients Z.n. RPE and PSA recurrence and SRT	**6.10** a. SRT shall be started as early as possible (PSA before SRT < 0.5 ng/ml). SRT = Salvage radiotherapy	**LoE 2-3** **Quality Objective:** Start SRT as often as possible with PSA <0.5ng/ml

PCa 8: Prevention of osteonecrosis of the jaw

Numerator: Number of patients with dental examination before starting therapy **Denominator:** All patients with prostate carcinoma and bisphosphonate o. denosumab therapy	**6.52** To prevent osteonecrosis of the jaw, a dental examination and any necessary dental rehabilitation shall take place before the administration of bisphosphonates or denosumab, as well as instruction and motivation of the patient to maintain above-average oral hygiene.	**LoE 3+** **Quality Objective:** Dental examination as often as possible before starting bisphosphonate or denosumab therapy

PCa 9: Postoperative complications after radical prostatectomy*

Numerator: Number of patients with complication Clavien-Dindo grade III or IV within the first 6 months after RPE **Denominator:** All patients with initial diagnosis of prostate carcinoma T1-2 N0 M0 and RPE	Based on a corresponding ICHOM indicator. Corresponds to the aim of the guideline: recording of postoperative complications.	Not a recommendation, but derived from a specific guideline objective. Justification requirement: 10% **Quality Objective:** As rare as possible Clavien-Dindo grade III or IV after RPE in localized prostate carcinoma

Notes:
Source for classification: [850]
Grade III complications requiring surgical, endoscopic or radiological intervention
Grade IIIa as before but without general anaesthesia
Grade IIIb as before but with general anaesthesia
Grade IV Life-threatening complication requiring intensive medical treatment
Grade IVa Failure of an organ
Grade IVb Multiple organ failure

PCa 7: Salvage radiotherapy for recurrent prostate cancer*

PCa 10: Complications after definitive radiotherapy*

Numerator: Number of patients with complication CTCAE Grade III or IV within the first 6 months after end of radiotherapy **Denominator:** All patients with first diagnosis of prostate cancer and definitive radiotherapy	Based on a corresponding ICHOM indicator. Corresponds to the aim of the guideline: recording of complications after definitive radiotherapy.	Not a recommendation, but derived from a specific guideline objective. **Quality Objective:** As rarely as possible CTCAE Grade III or IV after definitive radiotherapy
Notes: Source for classification: [13]		

* Indicator can be documented with the updated uniform basic oncology data set and the associated modules (as of September 2017).

27. Psychooncology

(Version 1.1, January 2014)

Quality indicator	Underlying recommendation/statement	Evidence base/comments
PSO 1: Structural requirements of psycho-oncological care areas: Cross-sectoral coordination of psycho-oncological care		
Numerator: Number of patients who received information about psycho-oncological support services **Denominator:** All cancer patients with initial diagnosis, recurrence or first distant metastasis*.	**4.3** Patient-oriented information about psycho-oncological support services shall be provided at an early stage and during the course of the disease. **8.7** Psychoeducational interventions shall be offered to people with cancer regardless of the level of distress.	**EC (4.3); LoE 1a (8.7)** Supplementary note: Definition of "psycho-oncological support service": psychosocial counselling, individual or group psychotherapeutic intervention, psychoeducational intervention, couples intervention, relaxation techniques, provided by the appropriately qualified persons. The aim of the indicator: The facility shall name concrete contacts for the patient as an example reference. This is intended to promote the formation of networks within and across facilities.

PSO 2: Structural requirements of psycho-oncological care areas: self-help groups

Numerator: Number of patients who received information about support services offered by cancer self-help groups/cancer self-help organizations **Denominator:** All cancer patients with initial diagnosis, recurrence or first distant metastasis*.	**4.2** Cancer patients and their relatives shall be informed about qualified support services offered by cancer self-help groups / cancer self-help organisations (discussions with people affected by the same disease, assistance in dealing with the disease, therapies and therapy consequences in everyday life) in every phase of the care process.	**EC** Supplementary note: The information can be conveyed by flyer, the flyer shall be handed over personally. In the flyer, the institution in question states specifically where which offer can be found and names contact persons.

PSO 3: Diagnostics: Screening, Diagnostic Procedures

Numerator: Number of patients with use of validated and standardized screening instruments (e.g. the Distress Thermometer or the HADS-D) **Denominator:** All cancer patients with initial diagnosis, recurrence or first distant metastasis*.	**7.3** Validated and standardized screening instruments shall be used to assess psychosocial stress. The distress thermometer or the HADS-D are recommended as screening instruments. In addition, the individual psychosocial support needs are to be inquired about. **7.2** All patients shall be screened for psychosocial stress. Psycho-oncological screening shall be performed as early as possible, at appropriate intervals, if clinically indicated, or repeatedly during the course of the disease if there is a change in the patient's disease status (e.g. recurrence or progression of the disease).	**EC** For literature on validated screening instruments with a defined cut-off (HADS-D, HSI: Distress Thermometer, FBK, PO-BADO, PHQ-9) see the long version of the guideline. Supplementary note: Validated screening instruments with a defined cut-off are: • Hospital Anxiety and Depression Scale (HADS-D) • -Hornheider Screening Instrument (HSI) • -Distress Thermometer (DT) • -Questionnaire on the Burden of Cancer Patients (FBK-23 and FBK-10) • Basic psycho-oncological documentation (PO-BADO, PO-BADO KF and PO-BADO breast cancer) • Patient Health Questionnaire - Depression Module (PHQ-9) The patient's refusal of screening shall be reported separately. If no screening was performed, it shall be checked whether a diagnostic

		interview was performed as an initial measure. If this is the case, it is considered as a performed screening.

PSO 4: Diagnostics: Diagnostic procedures

Numerator: Number of patients with a diagnostic interview to clarify psychosocial stress and psychological comorbidity **Denominator:** All cancer patients with initial diagnosis, recurrence or first distant metastasis and with positive screening for psychosocial distress*.	7.4 In case of positive screening and/or patient request, a diagnostic interview shall take place to clarify psychosocial stress and psychological comorbidity.	**EC** **Supplementary note:** Validated screening instruments with a defined cut-off are: Hospital Anxiety and Depression Scale (HADS-D) Hornheider Screening Instrument (HSI) Distress Thermometer (DT) Questionnaire on the Burden of Cancer Patients (FBK-23 and FBK-10) Basic psycho-oncological documentation (PO-BADO, PO-BADO KF and PO-BADO breast cancer) Patient Health Questionnaire - Depression Module (PHQ-9) Definition of "diagnostic interview": The diagnostic interview includes the identification of psychosocial stress, mental disorders and other problems with the aim of describing existing problems and disorders and their change. In addition, it is clarified whether these problems are subsyndromal or fulfil the criteria for a mental disorder. The clarification and classification of the existing problems and disorders is carried out according to a classification system (ICD-10 or DSM IV), whereby in the diagnosis of a clinically relevant comorbid disorder the differentiation from somatic complaints or an appropriate psychological

		reaction to the tumour disease as well as the appropriate consideration of biological-organic consequences of the cancer disease or treatment are to be taken into account. Actors: Psycho-oncology professionals

PSO 5: Psycho-oncological interventions: Concepts and general principles for the indication of psycho-oncological treatment.

Numerator: Number of patients offered individual and/or group psychotherapeutic intervention. **Denominator:** All cancer patients with initial diagnosis, recurrence or first distant metastasis and with adjustment disorder (ICD-10 F43.2.) *.	**8.5** Patients with adjustment disorder (identified through screening and further diagnostic testing) shall be offered patient-centred information and psychosocial counselling, as well as additional individual and/or group psychotherapeutic intervention.	**EC**

PSO 6: Psycho-oncological interventions: Concepts and general principles for the indication of psycho-oncological treatment, psychosocial counselling.

Numerator: Number of patients offered psychosocial counselling **Denominator:** All cancer patients with initial diagnosis, recurrence or first distant metastasis*.	**8.11** Psychosocial counselling shall be offered to cancer patients and their relatives in all phases of the disease, according to their needs and as early as possible. **8.2** Patients with no or low burden (determined by screening through further diagnostics) shall be offered patient-oriented information and psychosocial counselling.	**EC** **Supplementary note:** Psychosocial counselling shall be offered personally by social workers/social pedagogues and psycho-oncology specialists (cf. QI 2: the personal handing over of a flyer). Actors: social workers/ social pedagogues and psycho-oncology specialists

PSO 7: Patient-centred communication: measures for continuous education to improve the communicative competence of medical staff and their effectiveness

Numerator: All doctors and nurses with further education and training measures to improve their communicative competence **Denominator:** All doctors and nurses working in oncology	**11.5** Physicians and other professional groups working in oncology shall undergo further training to improve their communication skills.	**EC** Literature: Barth and Lannen (2011)[14] **Supplementary note:** Further continuous education and training measures to teach specific interviewing skills: Postgraduate; number of teaching units must be proven (e.g. certificate of participation). The training shall be at least 3 days (24 hours) in length. Reasons for the deviation of the QI from the guideline recommendation: In accordance with the prioritization of measures of the National Cancer Plan, the focus is on physicians and nurses, since these two

		professional groups are considered to have priority in patient care. In the case of psychotherapists, it can be assumed that skills in communication and interview management were taught in their respective basic training courses.

Legend:
* = This definition of the **Denominator** was made in order to enable uniform documentation in the first place. To avoid multiple documentation, the palliative situation is recorded by "first distant metastasis". The review shall take place at inpatient admission. The QIs are to be understood as "minimum standards", i.e. psycho-oncological interventions in situations other than those listed in the **Denominator** are explicitly not to be excluded by the indicator.

28. Supportive therapy

(Version 1.3, February 2020)

Quality indicator	Reference Recommendation	Evidence base/ further information
Supp 1: Antiemesis in highly emtogenic tumor therapy		
Numerator: Patients with administration of 5-HT3-RA and NK1-receptor antagonist and dexamethasone prior to 1st drug therapy **Denominator:** All patients with completed drug highly-emetogenic tumor therapy	**Acute Phase:** For one-day tumor therapy with an emesis risk > 90%, prophylaxis with a 5-HT3-RA, an NK1 receptor antagonist, and dexamethasone shall be given before chemotherapy. **Delayed Phase:** In the case of tumour therapy with an emesis risk > 90 %, prophylaxis with dexamethasone shall be given for a further 2-4 days after the end of the highly emetogenic tumour therapy. If the NK1 receptor antagonist aprepitant was part of the primary prophylaxis, it must be administered at 80 mg daily for 2 additional days. Fosaprepitant or netupitant/palonosetron shall only be administered on day 1 of tumour therapy.	**LoE 1a** **Quality Objective:** If possible, frequent administration of 5-HT3-RA u NK1 receptor antagonist u dexamethasone prior to the 1st drug treatment of the tumour
Notes: Highly emetogenic tumor therapy: anthracycline/cyclophosphamide combination; carmustine, cisplatin, cyclophosphamide ≥ 1500 mg/m2·dacarbazine, mechlorethamine, streptozotocin, hexamethylmelamine, procarbazine.		
Supp 2: Dental examination before bisphosphonates/denosumab		
Numerator:	For the prevention of osteonecrosis of the jaw, before	**LoE LA** **Quality Objective:**

Quality indicator	Reference Recommendation	Evidence base/ further information
Number of patients with dental examination before the start of Bisphosphonate or denosumab therapy **Denominator:** All patients with malignant Tm (= breast, prostate, lung carcinoma) and bisphosphonate or denosumab therapy	the administration of bisphosphonates or Denosumab • a dental examination and any necessary dental rehabilitation, and • the patient is instructed and motivated to maintain above-average (careful and regular) oral hygiene, as well as in the course • regular risk-adapted dental examinations take place.	Dental examination as often as possible before the start of Bisphosphonate or denosumab therapy
Notes: The dental examination also includes any necessary dental rehabilitation		

Supp 3: Dental examination before radiotherapy for KHT

Numerator: Patients with dental examination before starting therapy **Denominator:** All patients with KHT-Tm and curatively intended radiotherapy	For the prophylaxis of osteoradionecrosis in the head and neck region, the following measures shall be observed: before radiation therapy: • Dental rehabilitation under special conditions after radiation therapy: • Dental rehabilitation under special conditions, • masticatory rehabilitation with maximum protection of the mucous membrane and attention to special measures in the case of dental/maxillofacial surgery. • Measures Pre-/peri- and post-radiotherapy very good oral hygiene	**EC** **Quality Objective:** Dental examination as often as possible before starting therapy
Notes: • The dental examination includes the dental rehabilitation if necessary • Head and neck tumours: <u>all</u> tumours in the head and neck region		

29. Cervical carcinoma - diagnostics, therapy, aftercare

(Version 1.0, September 2014)

Quality indicator	Reference Recommendation	evidence base/ further information
ZxCa 1: Presentation in tumor conference		
Numerator: Number of patients with presentation at the tumor conference **Denominator:** All patients with initial diagnosis, recurrence or new distant metastasis of cervical carcinoma.	All patients with histologically proven cervical carcinoma shall be presented in an interdisciplinary tumor conference.	**EC** **Notes:** Participants of the tumor conference are gynecologist, pathologist, radiologist, radio-oncologist.
ZxCa 2: Information in the report of findings at initial diagnosis and tumor resection		
Numerator: Number of patients with reports of findings with information on: • histological type according to WHO • Grading • Detection/absence of lymphatic or venous intrusion (L- and V-status) • Detection/absence of perineural sheath infiltrates (Pn status) • Staging (pTNM and FIGO) in conized patients taking into account the conization findings • Depth of invasion and extension in mm for pT1a1 and pT1a2 • three-dimensional tumour size in cm (from pT1b1) minimum distance to the resection edges R classification (UICC)	**Tumour typing 8.1** Tumor typing shall be done according to the latest edition WHO classification. **Staging of cervical carcinoma 8.3** The staging shall follow the latest edition of the TNM classification. **Staging of cervical carcinoma 8.4** The diagnosis of microinvasive cervical carcinoma shall be based on the definition of the current edition of the WHO and TNM classification. **Trachelectomy 8.9** The morphological work-up shall be performed in such a way that all therapeutically and prognostically relevant parameters can be determined. The findings shall be based on the currently valid WHO classification for tumour typing and the current TNM classification for staging as well as the R classification (UICC). **8.10** The findings report shall include the following information:	**EC** **Note:** WHO classification: see [15]. (Status: 01.2014) TNM classification: see [16]

Quality indicator	Reference Recommendation	evidence base/ further information
Denominator: All patients with initial diagnosis of cervical carcinoma and tumor resection	• histological type according to WHO • Grading • Detection/absence of lymphatic or venous intrusion (L- and V- status) • Detection/absence of perineural sheath infiltrates (Pn status) • Staging (TNM) • Depth of invasion and extension in mm for pT1a1 and pT1a2 • three-dimensional tumour size in cm (from pT1b1) • minimum distance to the resection edges • R classification (UICC) **Preparation after radical hysterectomy and lymph node removal 8.11.** The morphological work-up shall be performed in such a way that all therapeutically and prognostically relevant parameters can be determined. The findings shall be based on the currently valid WHO classification for tumour typing and the current TNM classification for staging as well as the R classification (UICC). **8.13** The findings report shall include the following information: • histological type according to WHO • Grading • Detection/absence of lymphatic or venous intrusion (L- and V- status) • Detection/absence of perineural sheath infiltrates (Pn status) • Staging (TNM), in conized patients taking into account the conization findings • Depth of invasion and extension in mm for pT1a1 and pT1a2 • three-dimensional tumour size in cm (from pT1b1) • minimum distance to the resection edges • R classification (UICC)	

Quality indicator	Reference Recommendation	evidence base/ further information
ZxCa 3: Information in the report of findings in case of lymphonodectomy		
Numerator: Number of patients with report of findings with information on: • Number of affected LK in relation to removed LK • Assignment to the sampling site (pelvic/paraaortic) • Indication of the largest extension of the largest LK-metastasis in mm/cm • Indication of absence/evidence of capsular rupture of the LK metastasis. **Denominator:** All patients with cervical carcinoma and lymphonodectomy	**Preparation after radical hysterectomy and lymph node removal 8.15** In the case of lymphonodectomy specimens in the course of surgical therapy for cervical carcinoma, all removed lymph nodes shall be examined histologically. **Preparation after radical hysterectomy and lymph node removal 8.17** The findings report shall include the following information: Indication of the number of affected lymph nodes in relation to the number of removed lymph nodes in relation to the sampling location (pelvic/paraaortic). + appropriate background text: Requirements for the diagnostic report of lymphonodectomy specimens are: • Indication of the number of removed/examined LK in relation to the sampling location. • Indication of the number of affected lymph nodes in relation to the number of removed/examined lymph nodes in relation to the sampling location. • Indication of the largest extension of the largest LK-metastasis in mm/cm • Indication of absence/evidence of capsular rupture of the LK-metastasis	**EC**
ZxCa 4: cytological/histological lymph node staging		
Numerator: Number of patients with cytological/histological LK-staging **Denominator:** All patients with cervical carcinoma FIGO stage > = Ia2 - IVa	**Operative staging/sentinel to define tumor stage 9.2** The therapy shall depend on the histological tumor stage, verified by surgical staging or interventional diagnostics.	**EC, Consensus** **Notes:** Cytologic/histologic LK staging = for diagnostic purposes; no lymphonodectomy.

Quality indicator	Reference Recommendation	evidence base/ further information
ZxCa 5: Cisplatin-containing radiochemotherapy		
Numerator: Number of patients with cisplatin-containing radiochemotherapy **Denominator:** All patients with initial diagnosis of cervical carcinoma and primary radiochemotherapy	**Radio(chemo)therapy 11.4** In patients with cervical carcinoma, if primary radiotherapy is indicated from stage Ib2, it shall be given in combination with cisplatin-based chemotherapy.	**LoE 1++** Literature: [17, 18]
ZxCa 6: Adjuvant radio(chemo)therapy		
Numerator: Number of patients with adjuvant radio(chemo)therapy **Denominator:** All patients with initial diagnosis of cervical carcinoma and radical hysterectomy	Objective and question of the guidelineSurvey of the status quo of medical care, in particular with reference to quality indicator 6 on adjuvant radio(chemo)therapy, since no data exist on how many patients are treated adjuvantly with combined cisplatin-containing radio(chemo)therapy according to stage.	**Quality Objective** Current: Assessment of the status quo and long-term: Reduction of adjuvant therapy in favor of primary surgery alone or radio(chemo)-therapy alone in the risk population (unimodal therapy).
ZxCa 7: Histological backup		
Numerator: Number of patients with pre-therapeutic histological confirmation **Denominator:** All patients with cervical carcinoma and therapy of local recurrence	**Extended diagnostics for suspected recurrence 17.4** If a locoregional recurrence is suspected, histological confirmation shall be performed.	**EC**

ZxCa 8: Diagnosis of spread of local recurrence

Numerator: All patients with imaging diagnostics (CT thorax and abdomen and scalenus ultrasound) to exclude distant metastases **Denominator:** All patients with local recurrence of cervical carcinoma	**Diagnosis of local recurrence 18.1** In the event of local recurrence, appropriate imaging diagnostics shall be performed to exclude distant metastases in order to plan therapy.	**EC**

ZxCa 9: Exenteration

Numerator: Number of patients with local R0 resection **Denominator:** All patients with cervical carcinoma and tumour recurrence and exenteration	**Therapy of local recurrence 18.5** Exenteration for recurrence shall only be performed if resection in sano appears possible and there is no distant metastasis.	**EC**

30. Cervical carcinoma - prevention

(Version 1.1, March 2020)

Quality indicator	Reference Recommendation	Evidence base/ further information
PrevZxCa 1: Participation in cervical cancer screening		
Numerator: Women who participated in the screening **Denominator:** All women who have received an invitation for cervical cancer screening		**Quality Objective:** Participation in cervical cancer screening as often as possible
PrevZxCa 2: HPV and Pap smear within screening		
Numerator: Women with HPV and Pap smears within organized screening **Denominator:** All women with HPV and/or Pap smears.		**Quality Objective:** HPV and Pap smear as frequently as possible within the screening process
PrevZxCa 3: Repeated Pap test in screening		
Numerator: Women with a repeat Pap test within 36 months of the first test. **Denominator:** All women who participated in cervical cancer screening and had an unsuspicious Pap test		**Quality Objective**: Pap test shall be repeated as often as possible within 36 months after an inconspicuous Pap test in screening

Quality indicator	Reference Recommendation	Evidence base/ further information
PrevZxCa 4: Differential diagnostic test after screening in need of clarification Result		
Numerator: Women with subsequent differential diagnostic test (HPV, cytology, colposcopy, p16/Ki67) **Denominator:** All women with cervical cancer screening results requiring clarification		**Quality Objective:** Differential diagnostic test as often as possible after result of cervical cancer screening that requires clarification
Note: Result requiring clarification=Pap IIID2, IVa-p, IVa-g, IVb-p, IVb-g, V-p, V-g, V-e and V-x		
PrevZxCa 5: Therapy after abnormal differential diagnostic test in screening		
Numerator: Women with therapy within 6 months after abnormal test result **Denominator:** Women with abnormal differential diagnostic test in screening and thus indication for therapy		**Quality Objective:** If possible, frequent therapy within 6 months after abnormal differential diagnostic test in screening
PrevZxCa 6: Clarification colposcopy in case of abnormal Pap in cert. Dysplasia unit / consultation hour		
Numerator: Patients with clarification colposcopy due to Pap IIID2, IVa-p, IVa-g, IVb-p, IVb-g, V-p, V-g, V-e and V-x in DKG/DGG/AGO/AG-CPC/EFC certified gynaecological dysplasia consultation / gynaecological dysplasia unit **Denominator:** All patients with Pap IIID2, IVa-p, IVa-g, IVb-p, IVb-g, V-p, V-g, V-e and V-x	**10.8** In case of findings of the groups IIID2, IVa-p, IVa-g, IVb-p, IVb-g, V-p, V-g, V-e and V-x in the organized cytological screening, a colposcopic clarification shall be performed. **11.4** The colposcopy shall be performed as a clarification colposcopy in a dysplasia consultation / dysplasia unit certified in accordance with the requirements of the DKG/DGG/AGO/AG-CPC/EFC.	**Quality Objective:** If possible, frequent clarification colposcopy for Pap IIID2, IVa-p, IVa-g, IVb-p, IVb-g, V-p, V-g, V-e and V-x in certified gynaecological dysplasia consultation / gynaecological dysplasia unit 10.8 and 11.4: GCP

Quality indicator	Reference Recommendation	Evidence base/ further information
PrevZxCa 7: Preoperative clarification colposcopy before excision		
Numerator: Patients with an excision in whom a clarification colposcopy was performed preoperatively **Denominator:** All patients who underwent excision of the cervix uteri.	The representatives of the WG QI see a potential for improvement in the performance of the clarification colposcopy not only in the area of screening, but also in the area of therapy in the clinical routine.	**Quality Objective:** Preoperative clarification colposcopy before excision as often as possible
PrevZxCa 8: Knife conization as excision procedure		
Numerator: Pat. with excision by means of knife conisation **Denominator:** All patients who underwent excision of the cervix uteri	**14.1** Snare excision and laser excision shall be the methods of choice for the treatment of squamous and glandular cervical intraepithelial neoplasia.	**Quality Objective:** <10% Knife conisation as an excision procedure as rarely as possible A, ⊕⊖⊖⊖
PrevZxCa 9: CIN 3 in the incision margin after excision		
Numerator: Number of patients with CIN 3 in the incision margin **Denominator:** All patients with excision and histolog. Findings CIN 3	**14.13** R0 resection of CIN 3 shall be aimed for.	**Quality Objective:** rarely As rarely as possible CIN 3 in the incision margin after excision A, ⊕⊖⊖⊖
PrevZxCa 10: HPV test and cytology after therapy of a CIN 3		
Numerator: Pat. with HPV test and cytology within 12 mo after therapy **Denominator:** All patients 12 months after therapy (excision or ablation) of a first disease with CIN 3	**16.1** In the follow-up after therapy of a CIN/ ACIS a combined examination with HPV test and cytology shall be performed.	**Quality Objective:** HPV test and cytology as often as possible within 12 months after treatment of CIN 3 A, ⊕⊕⊖⊖

31. Literature

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