EAU-ESTRO-SIOG GUIDELINES ON PROSTATE CANCER

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Introduction

Please note that this text presents an abridged version of the full text Prostate Cancer (PCa) Guidelines and consultation of the more detailed, underlying document, is strongly advised. Prostate cancer is a complex disease, and, aside from disease characteristics, age, comorbidities and individual patient preference will impact treatment choice. All available management options need to be discussed in full with the patient.

Epidemiology and risk prevention

Prostate cancer is the most common cancer in males in Europe. It is a major health concern, especially in developed countries due to the greater proportion of elderly men in the general population, and the potential risk of over-treatment following early diagnosis. There are three well-established risk factors for PCa: increasing age, ethnic origin, and genetic predisposition. There is currently no high-level evidence that preventative measures may reduce the risk of PCa.

Classification and staging systems

The 2009 Tumour Node Metastasis (TNM) classification is used for staging (Table 1).

Table 1: 2009 TNM classification	
T - Primary tumour	
TX	Primary tumour cannot be assessed
T0	No evidence of primary tumour
T1	Clinically inapparent tumour not palpable or visible by imaging
T1a	Tumour incidental histological finding in 5% or less of tissue resected
T1b	Tumour incidental histological finding in more than 5% of tissue resected
T1c	Tumour identified by needle biopsy (e.g. because of elevated prostate-specific antigen (PSA) level)
T2	Tumour confined within the prostate[1]
T2a	Tumour involves one half of one lobe or less
T2b	Tumour involves more than half of one lobe, but not both lobes
T2c	Tumour involves both lobes
T3	Tumour extends through the prostatic capsule[2]
T3a	Extracapsular extension (unilateral or bilateral) including microscopic bladder neck involvement
T3b	Tumour invades seminal vesicle(s)
T4	Tumour is fixed or invades adjacent structures other than seminal vesicles: external sphincter, rectum, levator muscles, and/or pelvic wall
N - Regional lymph nodes[3]	
NX	Regional lymph nodes cannot be assessed
N0	No regional lymph node metastasis
N1	Regional lymph node metastasis[4]

M - Distant metastasis[5]	
MX	Distant metastasis cannot be assessed
M0	No distant metastasis
M1	Distant metastasis
M1a	Non-regional lymph node(s)
M1b	Bone(s)
M1c	Other site(s)

[1] *Tumour found in one or both lobes by needle biopsy, but not palpable or visible by imaging, is classified as T1c.*

[2] *Invasion into the prostatic apex, or into (but not beyond) the prostate capsule, is not classified as pT3, but as pT2.*

[3] *The regional lymph nodes are the nodes of the true pelvis, which essentially are the pelvic nodes below the bifurcation of the common iliac arteries.*

[4] *Laterality does not affect the N-classification.*

[5] *When more than one site of metastasis is present, the most advanced category should be used.*

Table 2: EAU risk groups for biochemical recurrence of localised and locally advanced PCa

Definition			
Low-risk	**Intermediate-risk**	**High-risk**	
PSA < 10 ng/mL and GS < 7 and cT1-2a	PSA 10-20 ng/mL or GS 7 or cT2b	PSA > 20 ng/mL or GS > 7 or cT2c	any PSA any GS cT3-4 or cN+
Localised			**Locally advanced**

GS = Gleason score; PSA = prostate-specific antigen.

Guidelines for screening and early detection	LE	GR
Do not subject men to PSA testing without counselling on the potential risks and benefits.	3	B
Offer an individualised risk-adapted strategy for early detection to a well-informed man with a good performance status and a life expectancy of at least 10-15 years.	3	B
Offer early PSA testing in men at elevated risk of having PCa: • men > 50 years of age; • men > 45 years of age and a family history of PCa; • African-Americans > 45 years of age; • men with a PSA level of > 1 ng/mL at 40 years of age; • men with a PSA level of > 2 ng/mL at 60 years of age.	2b	A
Offer a risk-adapted strategy (based on initial PSA level), with follow-up intervals of 2 years for those initially at risk: • men with a PSA level of > 1 ng/mL at 40 years of age; • men with a PSA level of > 2 ng/mL at 60 years of age. Postpone follow-up to 8 years in those not at risk.	3	C
Decide on the age at which early diagnosis of PCa should be stopped based on life expectancy and performance status; men who have a life expectancy of < 15-years are unlikely to benefit.	3	A

PSA = prostate-specific antigen.

Diagnostic Evaluation

Clinical diagnosis

Prostate cancer is usually suspected on the basis of digital rectal examination (DRE) and/or PSA levels. Definitive diagnosis depends on histopathological verification of adenocarcinoma in prostate biopsy cores or unexpected discovery in specimens from transurethral resection of the prostate or prostatectomy for benign prostatic enlargement.

The decision whether to proceed with further diagnostic or staging work-up is guided by which treatment options are available to the patient, taking the patient's age and comorbidity into consideration. Procedures that will not affect the treatment decision can usually be avoided.

A biopsy pathology report includes the type of carcinoma and parameters describing its extent (e.g. proportion of positive cores, percentage or mm carcinoma involvement per core) as well as Gleason score per biopsy site and global Gleason score. Reporting of a radical prostatectomy specimen includes type of carcinoma, global Gleason score, pathological stage and surgical margin status. Recently, the ISUP-WHO 2014 grade groups were adopted which allow patients to better understand the behaviour of their diagnosed prostate carcinoma, while separating Gleason score 7 adenocarcinoma into two prognostically very distinct categories; grade group 2 for Gleason score 7 (3 + 4) and grade group 3 for Gleason score 7 (4 + 3) (see Table 3). This ISUP-WHO 2014 grade grouping will gradually be introduced into the standard pathology reporting.

Table 3: ISUP 2014 grade groups	
Gleason score	**Grade group**
2-6	1
7 (3 + 4)	2
7 (4 + 3)	3
8 (4 + 4) or (3 + 5) or (5 + 3)	4
9-10	5

ISUP = International Society of Urological Pathology.

Guidelines for the clinical diagnosis of PCa	LE	GR
Base the decision to perform a biopsy on PSA testing and DRE.	2b	A
Use a local anaesthetic by periprostatic infiltration for prostate needle biopsies.	1a	A
For initial diagnosis, perform a core biopsy of 10–12 systematic transrectal or transperineal peripheral zone biopsies under ultrasound guidance.	2a	B
Perform transrectal prostate needle biopsies under antibiotic protection.	1b	A
Do not initially offer transition zone biopsies due to low detection rates.	2b	B
Use the additional diagnostic options in asymptomatic men with a normal DRE and a PSA between 2.0 and 10 ng/mL (risk calculator, or an additional serum or urine-based test [e.g. PHI, 4Kscore or PCA3] or imaging).	3	C
Do not use transurethral resection of the prostate as a tool for cancer detection.	2a	A
Perform one set of repeat biopsies for persistent indications for PCa (abnormal DRE, elevated PSA or histopathological findings suggestive of malignancy at initial biopsy).	2a	B

Ensure that prostate core biopsies from different sites are submitted separately for processing and pathology reporting.	3	A
Use the ISUP 2005 modified Gleason grading system for grading of PCa.	2a	A
Adhere to the 2010 ISUP consensus meeting Guidelines for processing and reporting of prostatectomy specimens.	3	A

DRE = digital rectal examination; ISUP = International Society of Urological Pathology; PCA3 = prostate cancer gene 3; PHI = Prostate Health Index; PSA = prostate-specific antigen.

Guidelines for processing prostatectomy specimens	**LE**	**GR**
Ensure total embedding, by conventional (quadrant) or whole-mount sectioning.	3	C
Ink the entire surface before cutting, to evaluate the surgical margin.	3	A
Examine the apex and base separately, using the cone method with sagittal or radial sectioning.	3	A

Recommendations for imaging - repeat biopsy	**LE**	**GR**
Before repeat biopsy, perform mpMRI when clinical suspicion of PCa persists in spite of negative biopsies.	1a	A
During repeat biopsy include systematic biopsies and targeting of any mpMRI lesions seen.	2a	B

mpMRI = multiparametric magnetic resonance imaging.

Guidelines for staging of PCa

Any risk group staging	LE	GR
Do not use CT and TRUS for local staging.	2a	A

Low-risk localised PCa	LE	GR
Do not use additional imaging for staging purposes.	2a	A

Intermediate-risk PCa	LE	GR
In predominantly Gleason pattern 4, metastatic screening, include at least cross-sectional abdominopelvic imaging and a CT/MRI and bone-scan for staging purposes.	2a	A*
In predominantly Gleason pattern 4, use prostate mpMRI for local staging and metastatic screening.	2b	A

High-risk localised PCa/ High-risk locally advanced PCa	LE	GR
Use prostate mpMRI for local staging.	2b	A
Perform metastatic screening including at least cross-sectional abdominopelvic imaging and a bone-scan.	2a	A

**Upgraded following panel consensus.*
CT = computed tomography; mpMRI = multiparametric magnetic resonance imaging; TRUS = transrectal ultrasound.

Disease Management

Deferred treatment

Many men with localised PCa will not benefit from definitive treatment, and 45% of men with PSA-detected PCa would be

candidates for deferred management. In men with comorbidity and limited life expectancy, treatment of localised PCa may be deferred to avoid loss of quality of life (QoL).

Guidelines overview - Primary treatment of PCa

Primary treatment of PCa			GR
General comments	Discuss several treatment modalities (active surveillance, surgery and radiotherapy) with patients suitable for such treatments.		A*
	In patients who are surgical candidates for radical prostatectomy, discuss all approaches (i.e. open, laparoscopic or robotic) as acceptable treatment options since none have clearly shown superiority in terms of functional or oncological results.		A
	Offer EBRT to all risk groups of non-metastatic PCa.		A
	Offer IMRT for definitive treatment of PCa by EBRT.		A
	Treatment	**Comment**	
Low risk PCa	**Watchful waiting**	Offer WW to patients not eligible for local curative treatment and those with a short life expectancy.	A
		While on WW, base the decision to start non-curative treatment on symptoms and disease progression.	B

	Active surveillance	Offer AS to patients with the lowest risk of cancer progression: > 10 years life expectancy, cT1/2, PSA ≤ 10 ng/mL, biopsy Gleason score ≤ 6, ≤ 2 positive biopsies, minimal biopsy core involvement (≤ 50% cancer per biopsy).	A
		Base follow-up on DRE, PSA and repeat biopsies. The optimal follow-up interval is still unclear.	A
	Radical prostatectomy	Offer RP to patients with a life expectancy > 10 years.	A
		Offer a nerve-sparing surgery in pre-operatively potent patients with low risk of extracapsular disease (T1c, GS < 7 and PSA < 10 ng/mL, or refer to Partin tables/nomograms).	B
		Do not perform LND in low-risk PCa	A
	Radiotherapy	In low-risk PCa, the total dose should be 74 to 78 Gy.	A
		In patients with low-risk PCa, without a previous TURP and with a good IPSS and a prostate volume < 50 mL, offer LDR brachytherapy.	A

	Cryotherapy, HIFU	Only offer cryotherapy and HIFU within a clinical trial setting. The lack of long-term efficacy compared to standard modality has to be discussed with patients.	C
	Focal treatment	Do not offer focal therapy of PCa as a therapeutic alternative outside clinical trials.	A
	Androgen suppression	Unsuitable.	A
Intermediate risk PCa	**Watchful waiting**	Offer WW to patients not eligible for local curative treatment and those with a short life expectancy.	A
	Active surveillance	Not an option.	A
	Radical prostatectomy	Offer RP to patients with a life expectancy > 10 years.	A
		Offer a nerve-sparing surgery in pre-operatively potent patients with low risk of extracapsular disease (T1c, GS < 7 and PSA < 10 ng/mL, or refer to Partin tables/nomograms).	B
		In intermediate-risk, extracapsular disease, use mpMRI as a decision tool to select patients for nerve-sparing procedures.	B
		Perform an eLND if the estimated risk for positive LNs exceeds 5%.	B
		Do not perform a limited LND.	A

		In patients with pT3,N0M0 PCa and an undetectable PSA following RP, discuss adjuvant EBRT because it at least improves BFS.	A
		Inform patients with pT3,N0M0 PCa and an undetectable PSA following RP about salvage irradiation as an alternative to adjuvant irradiation when PSA increases.	A
		Do not offer adjuvant HT for pN0.	
	Radiotherapy	In intermediate-risk PCa use a total dose of 76-78 Gy, in combination with short-term ADT (4-6 mo).	A
	Androgen suppression monotherapy	No place in asymptomatic patients.	A
High risk PCa	**Watchful waiting**	**High risk localised**: Offer WW to patients not eligible for local curative treatment and those with a short life expectancy.	
		High risk locally advanced: In locally advanced M0 patients unwilling or unable to receive any form of local treatment, offer a deferred treatment policy using ADT as mono-therapy to asymptomatic patients with a PSA-DT > 12 months and a PSA < 50 ng/mL and non-poorly differentiated tumour.	A

	Active surveillance	Not appropriate.	A
	Radical prostatectomy	Do not offer NHT before RP.	A
		Perform an eLND in high-risk PCa.	A
		Do not perform a limited LND.	A
		High risk localised: Offer RP in a multimodality setting to patients with high-risk localised PCa and a life expectancy of > 10 years.	B
		Offer nerve-sparing surgery in pre-operatively potent patients with low risk for extracapsular disease (refer to Partin tables/ nomograms).	B
		In high-risk disease, use mpMRI as a decision-making tool to select patients for nerve-sparing procedures.	B
		High risk locally advanced: Offer RP in a multimodality setting to highly selected patients with locally advanced PCa (cT3b-T4 N0 or any T N1). Do not consider nerve sparing surgery.	C
		In patients with pT3,N0M0 PCa and an undetectable PSA following RP, discuss adjuvant EBRT because it at least improves BFS.	A

		Inform patients with pT3,N0M0 PCa and an undetectable PSA following RP about salvage irradiation as an alternative to adjuvant irradiation when PSA increases.	A
	Radiotherapy	In patients with high-risk localised PCa, use a total dose of 76-78 Gy in combination with long-term ADT (2-3 years is recommended).	A
		In patients with locally advanced cN0 PCa, offer RT in combination with long-term ADT (2-3 years is recommended).	A
	Androgen suppression monotherapy	Reserved for those patients unwilling or unable to receive any form of local treatment and that are either symptomatic or asymptomatic with a PSA-DT < 12 months and a PSA > 50 ng/mL and a poorly differentiated tumour.	A
N1 patients			
cN1	In patients with cN+ PCa, offer pelvic EBRT in combination with immediate long-term ADT.		B
pN1 after eLND	Offer adjuvant ADT for node-positive (pN+).		A
	Offer adjuvant ADT with additional radiotherapy.		B
	Offer observation (expectant management) to a patient after eLND and ≤ 2 nodes showing microscopic involvement, with a PSA < 0.1 ng/mL and absence of extranodal extension.		B

Metastatic PCa	**Watchful waiting**	In M1 asymptomatic patients, deferred castration should be discussed with a well-informed patient.	B
	Active surveillance	Unsuitable.	A
	Radical prostatectomy	Unsuitable outside clinical trial.	A
	Radiotherapy to the prostate	Unsuitable outside clinical trial.	A
	Androgen suppression	Offer surgical or medical castration (LHRH agonist or antagonist).	A
		Offer castration combined with chemotherapy to all patients whose first presentation is M1 disease and who are fit enough for chemotherapy.	A
		Offer castration alone with or without an antiandrogen to patients unfit for, or unwilling to consider castration combined with chemotherapy.	A
		Do not offer castration combined with local treatment/ other new hormonal treatments (abiraterone acetate or enzalutamide) outside clinical trials.	A
		In M1 asymptomatic patients, offer immediate castration to defer progression to a symptomatic stage and prevent serious disease progression-related complications.	A

		In M1 symptomatic patients, offer immediate castration to palliate symptoms and reduce the risk for potentially catastrophic sequelae of advanced disease (spinal cord compression, pathological fractures, urethral obstruction, extra-skeletal metastases).	A
		In M1 patients treated with an LHRH agonist, offer short-term administration of anti-androgens to reduce the risk of the 'flare-up' phenomenon.	A
		Start anti-androgens used for 'flare-up' prevention on the same day as an LHRH analogue is started or for up to 7 days before the first LHRH analogue injection if the patient has symptoms). Treat for four weeks.	A
		Do not offer anti-androgen monotherapy in M1 patients.	A
		Offer LHRH antagonists, especially in patients with an impending spinal cord compression or bladder outlet obstruction.	B
		In asymptomatic M1 patients, offer intermittent treatment to highly motivated patients, with a major PSA response after the induction period.	B

		In M1 patients follow the schedules used in published clinical trials on timing of intermittent treatment. Stop treatment when the PSA level is < 4 ng/mL after 6-7 months of treatment. Resume treatment when the PSA level is > 10-20 ng/mL (or back to the original level, if < 20 ng/mL).	C
		In M1 patients, offer combined treatment with LHRH agonists and NSAA when an intermittent modality is used.	A

**Upgraded following panel consensus.*
ADT = androgen deprivation therapy; AS = active surveillance; BFS = biochemical progression-free survival; DRE = digital rectal examination; EBRT = external beam radiation therapy; HIFU = high-intensity focused ultrasound; HT = hormonal therapy; IMRT = intensity-modulated radiotherapy; IPSS = International Prostate Symptom Score; LDR = low-dose-rate; LHRH = luteinising-hormone-releasing hormone; eLND = (extended) lymph node dissection; LN = lymph node; mpMRI = multiparametric magnetic resonance imaging; NHT = neoadjuvant hormonal therapy; NSAA = non-steroidal anti-androgen; PSA = prostate-specific antigen; PSA-DT = PSA doubling time; RP = radical prostatectomy; RT = radiation therapy; TURP = transurethral resection of the prostate; WW = watchful waiting.

Guidelines for the treatment of senior adults (> 70 years of age)

Assessment	GR
Perform systematic health status screening in senior adults with localised PCa.	A
Use the G8 screening tool for health status screening.	A
Perform a full specialist geriatric evaluation in patients with G8 score ≤ 14.	A
Treatment options for senior adults according to their health status: 1. Offer standard treatment to fit or healthy older men; 2. Offer standard treatment to vulnerable patients (reversible impairment) after resolution of geriatric problems; 3. Offer adapted treatment to frail patients (irreversible impairment); 4. Offer only symptomatic palliative treatment to patients who are too sick with terminal illness.	B

Treatment	LE	GR
Localised disease		
Offer standard treatment to fit and vulnerable senior adults (after status optimisation) with a life expectancy > 10 years.	2b	A
Offer individualised treatment based on life expectancy, symptoms and risk factors to senior adults with a life expectancy < 10 years.	2b	A
In frail or 'too–sick' senior adults, offer immediate ADT only for symptom palliation.	1b	A
Offer minimally invasive energy-ablative therapies only to selected fit and vulnerable senior adults with intermediate-risk disease.	3	B

Advanced disease (locally advanced / metastatic disease)		
Evaluate bone mineral status and prevent osteoporosis-related fractures in senior adults.	2b	A
Offer new chemotherapeutic and hormonal agents to fit and vulnerable adults.	1b	B

ADT = androgen deprivation therapy.

Castrate resistant PCa

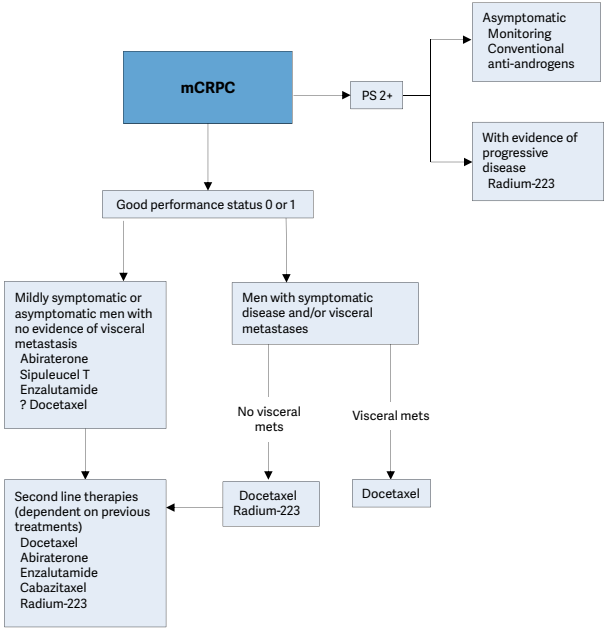
No definitive strategy regarding treatment choices (which drug/drug family first) can be devised.

Castrate resistant status	**GR**
Ensure that testosterone levels are confirmed as < 50 ng/mL, before diagnosing CRPC.	A
Do not treat patients for non-metastatic CRPC outside of a clinical trial.	A
Counsel, manage and treat patients with mCRPC in a multidisciplinary team.	A
In men treated with maximal androgen blockade, stop anti-androgen therapy once PSA progression is documented. *Comment: Four to six weeks after discontinuation of flutamide or bicalutamide, an eventual anti-androgen withdrawal effect will be apparent.*	A
Treat patients with mCRPC with life prolonging agents. Base the choice of first line treatment on the performance status, symptoms, comorbidities and extent of disease (alphabetical order: abiraterone, docetaxel, enzalutamide, radium-223, sipuleucel-T).	A
Offer patients with mCRPC who are candidates for cytotoxic therapy docetaxel with 75 mg/m^2 every 3 weeks.	A

In patients with mCRPC and progression following docetaxel chemotherapy, offer further life-prolonging treatment options, which include cabazitaxel, abiraterone, enzalutamide and radium-223.	A
Offer bone protective agents to patients with skeletal metastases to prevent osseous complications. However, the benefits must be balanced against the toxicity of these agents, and jaw necrosis, in particular, must be avoided.	A
Offer calcium and vitamin D supplementation when prescribing either denosumab or bisphosphonates.	A
Treat painful bone metastases early on with palliative measures such as EBRT, radionuclides, and adequate use of analgesics.	B
In patients with spinal cord compression, start immediate high-dose corticosteroids and assess for spinal surgery followed by irradiation. Offer radiation therapy alone if surgery is not appropriate.	A

EBRT = external beam radiation therapy; mCRPC = metastatic castrate-resistant prostate cancer; PSA = prostate-specific antigen.

Figure 1: Flowchart of the potential therapeutic options after PSA progression following hormonal therapy in metastatic patients.



PS = performance status; mCRPC = metastatic castrate resistant prostate cancer; mets = metastases.

Guidelines for supportive care of mCRPC

These recommendations are in addition to appropriate systemic therapy.

Recommendations	LE	GR
Offer bone protective agents to patients with skeletal metastases to prevent osseous complications. However, the benefits must be balanced against the toxicity of these agents, and jaw necrosis in particular must be avoided.	1a	B
Prescribe calcium and vitamin D supplementation when prescribing either denosumab or bisphosphonates.	1b	A
Treat painful bone metastases early on with palliative measures such as external beam radiotherapy, radionuclides, and adequate use of analgesics.	1a	B
In patients with spinal cord compression start immediate high-dose corticosteroids and assess for spinal surgery followed by irradiation. Offer radiation therapy alone if surgery is not appropriate	1b	A

Follow-up

Follow-up after treatment with curative intent

- After RP, PSA should be undetectable (< 0.1 ng/mL). A PSA of > 0.1 ng/mL after RP is a signal of residual prostate tissue. After an undetectable PSA is obtained following RP, a PSA > 0.2 ng/mL, and rising, is associated with recurrent disease.
- After radiotherapy, an increase in PSA > 2 ng/mL above the nadir, rather than a specific threshold value, is the most reliable sign of recurrence.
- Palpable nodules and increasing serum PSA are often signs of local recurrence.

Guidelines for follow up after treatment with curative intent	**GR**
Routinely follow-up asymptomatic patients, by obtaining a disease-specific history and serum PSA measurement supplemented by DRE. These should be performed at 3, 6 and 12 months after treatment, then every 6 months until 3 years, and then annually.	B
Imaging to detect local recurrence is only recommended if it affects treatment planning. Biopsy is usually not necessary before second-line therapy.	B
Do not routinely offer bone scans and other imaging modalities to asymptomatic patients if there are no signs of biochemical relapse. In case patients have bone pain or other symptoms of progression, re-staging should be considered irrespective of serum PSA level.	B

DRE = digital rectal examination; PSA = prostate-specific antigen.

Guidelines for follow-up during hormonal treatment	GR
Evaluate patients at 3 - 6 months after the initiation of treatment.	A
As a minimum, tests should include serum PSA measurement, DRE, serum testosterone, and careful evaluation of symptoms in order to assess the treatment response and side effects.	A
In patients undergoing intermittent androgen deprivation, monitor PSA and testosterone at fixed intervals during the treatment pause (monthly or at three month intervals).	A
Adapt follow-up to the individual patient, according to stage of disease, prior symptoms, prognostic factors and the treatment given.	A
In patients with stage M0 disease with a good treatment response, schedule follow-up every 6 months. As a minimum requirement, include a disease-specific history, DRE and serum PSA determination in the diagnostic work-up.	A
In patients with stage M1 disease with a good treatment response, schedule follow-up every 3 to 6 months. As a minimum requirement, include a disease-specific history, DRE, serum PSA, haemoglobin, serum creatinine and alkaline phosphatase measurements in the diagnostic work-up. The testosterone level should be checked, especially during the first year.	A
Counsel patients (especially with M1b status) about the clinical signs suggestive of spinal cord compression.	A
When disease progression occurs, or if the patient does not respond to treatment, adapt/individualise follow up.	A

In patients with suspected progression, assess the testosterone level. By definition, CRPC definition requires a testosterone level < 50 ng/mL (< 1 mL/L).	B
Do not offer routine imaging to otherwise stable patients.	B

CRPC = castrate-resistant prostate cancer; DRE = digital rectal examination; PSA = prostate-specific antigen.

This short booklet text is based on the more comprehensive EAU Guidelines (ISBN 978-90-79754-98-4), available to all members of the European Association of Urology at their website, http://www.uroweb.org.