

Stellschrauben der Versorgungsstruktur

Innovation als Changemaker

Theranostik

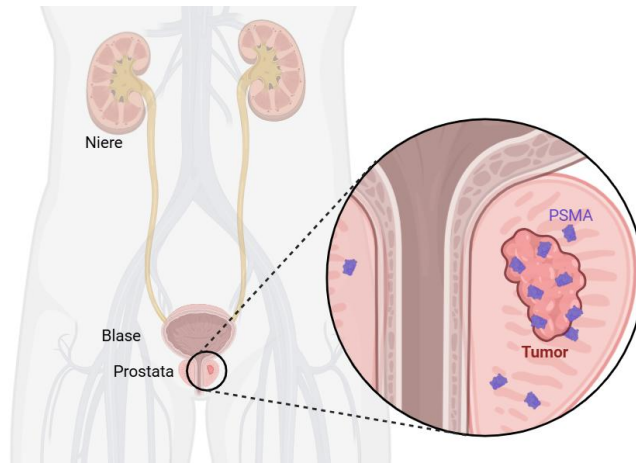
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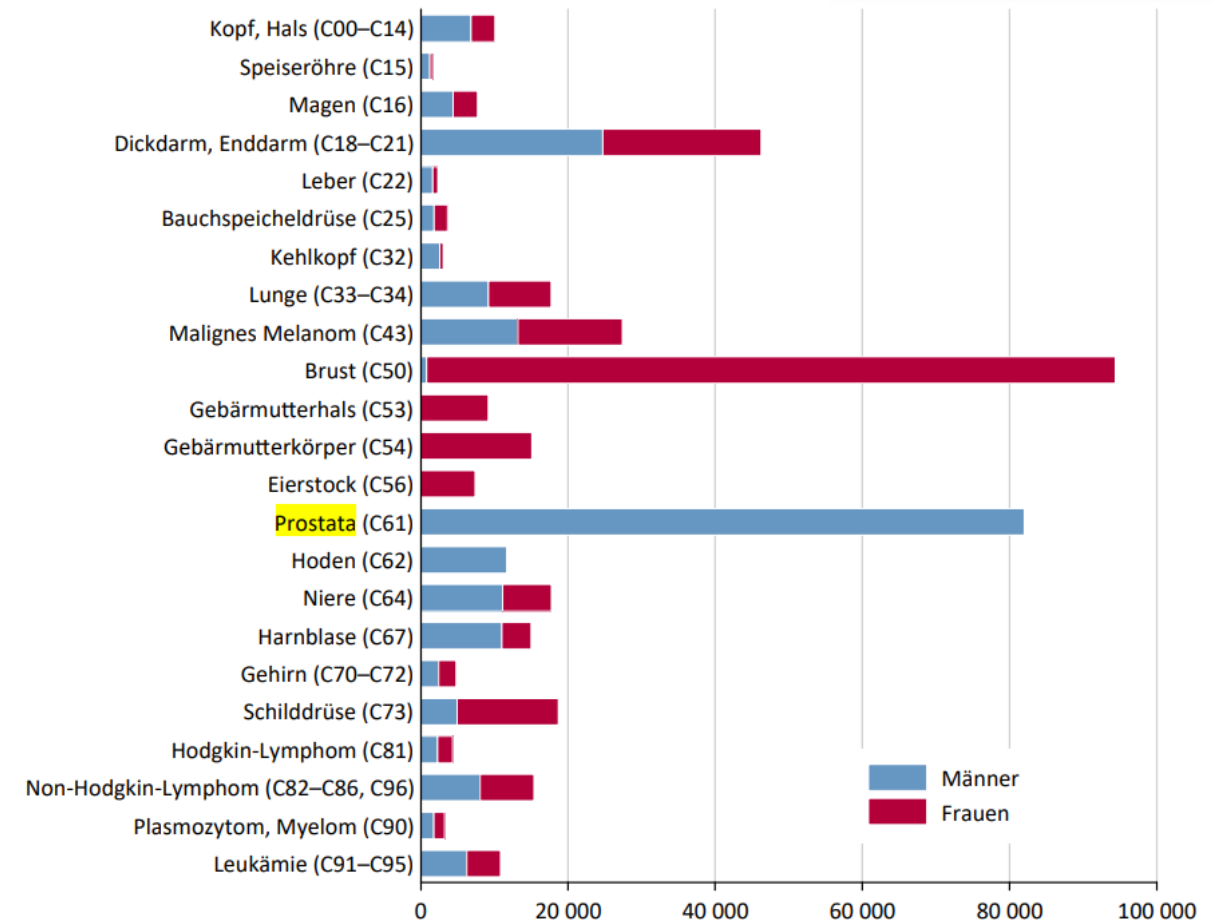
Wo gibt es die größten Herausforderungen?

Beispiel Prostatakarzinom



Krebsprävalenz

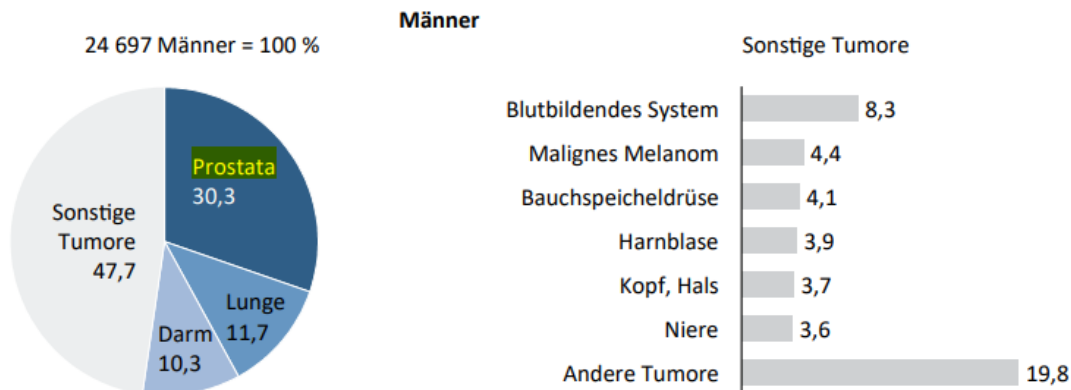
nach ausgewählten Lokalisationen und Geschlecht, am 31.12.2023



Q: STATISTIK AUSTRIA, Österreichisches Krebsregister (Stand 10.01.2025) und Todesursachenstatistik. – Zugrunde liegende Zahlen siehe Tabelle auf Seite 18.

Die häufigsten Tumorlokalisationen nach Geschlecht

2023



Wo gibt es die größten Herausforderungen?

Beispiel Prostatakarzinom

innovatives diagnostisch-therapeutisches Konzept
Theranostik



Patientenperspektive: einfach durchzuführen,
hoch wirksam und hervorragend verträglich

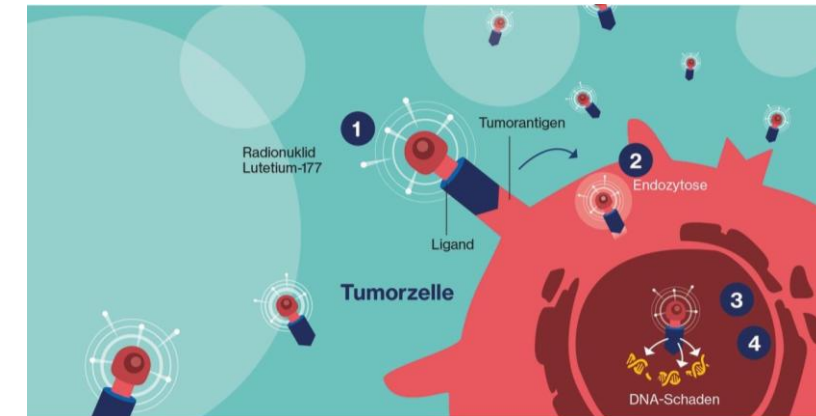


ausschließlich durch das klinische Fach
Nuklearmedizin durchzuführen

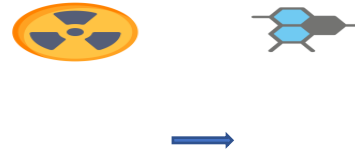


Bewältigung großer **Patientenzahlen** in den
nächsten Jahren

strukturelle (Verfügbarkeit!), (strahlenschutz)-
rechtliche & wirtschaftliche Rahmenbedingungen



Prinzip der Theranostik



Koppelung von diagnostischen und therapeutischen radioaktiven Tracern an bestimmten Biomarker



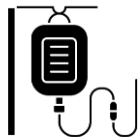
1. Lokalisation – „*Theranostics begins with diagnostics*“

Injektion einer kleinen Menge eines geeigneten radioaktiven Tracers, der spezifisch an Krebszellen bindet



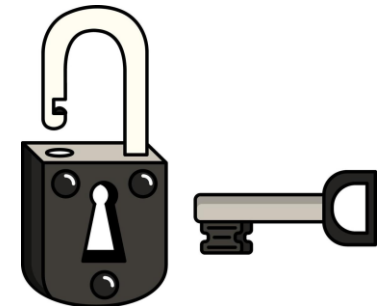
Darstellung, wo sich der Krebs befindet, da der Tracer in Bereichen mit Krebszellen am aufgenommenen Bild leuchtet.

2. Tumorthherapie



Sobald die Krebszellen lokalisiert sind, wird ein therapeutisches Medikament verabreicht, das direkt zu ihnen gelangt und gezielte Strahlung abgibt.

zielt auf den selben Tumor ab und bindet an die gleichen spezifischen biologischen Marker



Theranostik in der praktischen Anwendung

verwendet radioaktive Tracer

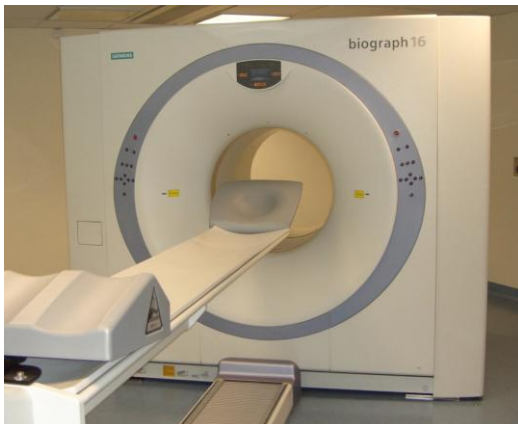
diagnostisches
Radiopharmakon

chemisch ähnliches
therapeutisches
Radiopharmakon

GA68 - PSMA



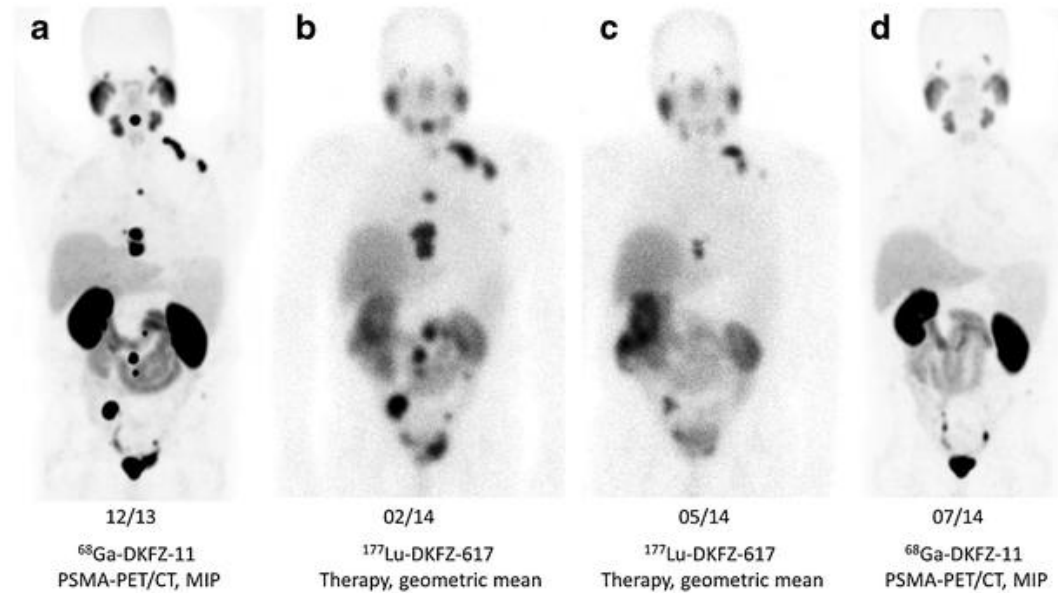
LU177 - PSMA



Medizinische Anwendung von ionisierender Strahlung

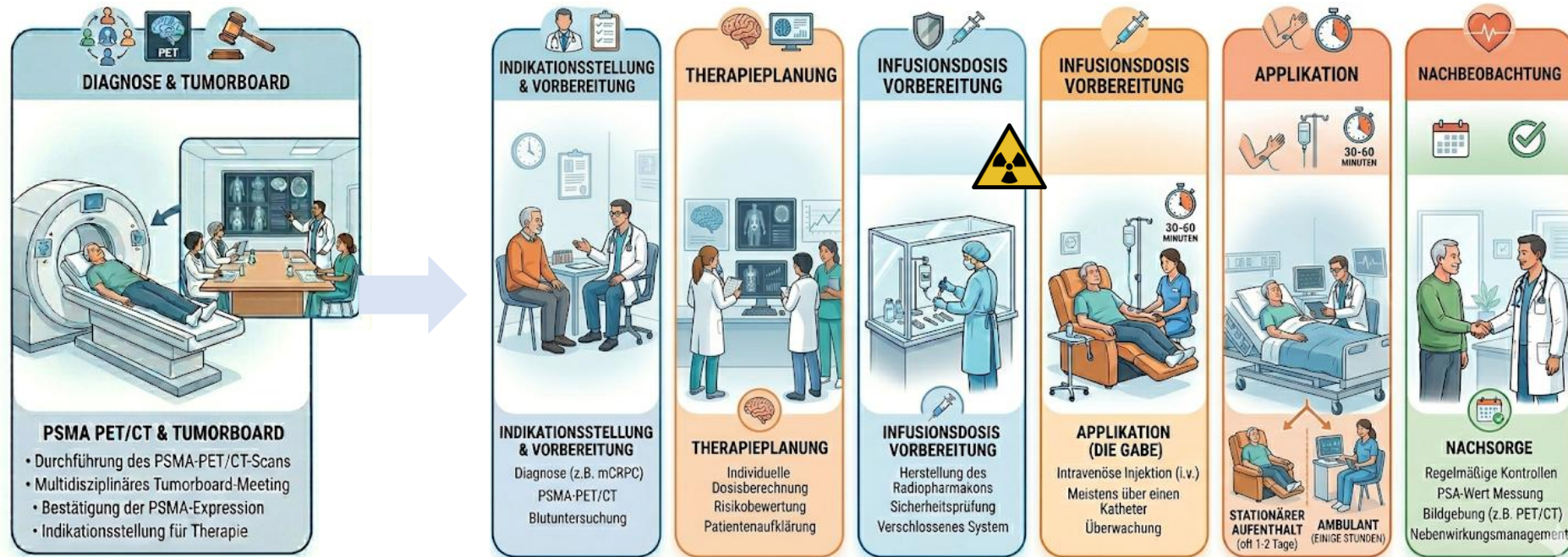
- Patienten mit **Prostatakarzinom** exprimieren in mehr als 90% das Prostata-spezifische Membranantigen (PSMA) an Ihrer Tumorzelloberfläche.
- In den letzten Jahren konnte mittels PSMA-PET/CT gezeigt werden, dass vor allem bei einem biochemischen PSA-Rezidiv bzw. ein ausgedehnterer Tumorbefall früher sichtbar gemacht werden kann und so eine Behandlungsänderung in bis zu 60% der Patienten bewirken kann.
- Mit der ^{177}Lu -PSMA-617 Radioligandentherapie (Pluvicto[®]) steht nun ein von der FDA und von der EMA zugelassenes Präparat zur Verfügung, das in einer Phase 3 Studie (Vision Trial) zeigen konnte, dass das mediane progressionsfreie Überleben im Vergleich zur Kontrollgruppe um 4,3 Monate statistisch signifikant verlängert wird.

Bsp. Ga-68 PSMA PET CT/ Lu-177 PSMA Therapie- begleitende Bildgebung



Therapie mit insgesamt 7.4 GBq Lu-177-PSMA

Organisation und Ablauf einer PSMA RLT



4-6 Zyklen,
alle 6 Wochen
PET/CT Zwischenstaging

PSMA RLT – eine international anerkannte Therapieoption bei Patienten mit metastasiertem Prostatakarzinom

Use of ¹⁷⁷Lu prostate-specific membrane antigen therapy in metastatic castration-resistant prostate cancer

Joint statement of the Austrian Society of Nuclear Medicine and Theranostics and the Austrian Society of Urology and Andrology

Table 1 EAU, ESMO, NCCN, AUA and EANM/SNMMI treatment recommendations summarized

Guideline	Recommendation
EAU Guidelines on Prostate Cancer 2024 [26]	Offer ¹⁷⁷ Lu-PSMA-617 to pre-treated mCRPC patients with ≥1 highly PSMA expressing metastatic lesion
ESMO updated treatment recommendations for prostate cancer 2023 [27]	In mCRPC patients, who have received an ARTA and docetaxel, the following treatments should be considered: ¹⁷⁷ Lu-PSMA-617 (with cancer expressing PSMA on PSMA-PET and without PSMA non-expressing lesions) Cabazitaxel
NCCN Guidelines Recommendations on Systemic Therapy for M1 CRPC AdenoCa 2023 [28]	In mCRPC, after progression on docetaxel and an ARTA, useful in certain circumstances: ¹⁷⁷ Lu-PSMA-617 (≥1 PSMA-positive lesion and/or metastatic disease that is predominately PSMA-positive and with no dominant PSMA-negative metastatic lesions)
AUA Guidelines on Advanced Prostate Cancer, Guideline Statement 32 Amended 2023 [29]	¹⁷⁷ Lu-PSMA-617 should be offered in patients with progressive mCRPC, previously treated with docetaxel and an ARTA, with a positive PSMA-PET imaging
EANM/SNMMI	In mCRPC PSMA-positive patients, who progressed at least after an ARTA or alternative treatment options have been exhausted or are contraindicated on an individual patient basis
German Guidelines on Prostate Cancer (S3 Leitlinie Prostatakarzinom) 2024	mCRPC patients with progressive disease, in a good general condition, after docetaxel and one ARTA should be offered: Cabazitaxel ¹⁷⁷ Lutetium-PSMA-617 (¹⁷⁷ Lu vipivotide tetraxetan)
ARTA androgen receptor targeted agents, mCRPC metastatic castration-resistant prostate cancer, PSMA Prostate-specific membrane antigen	



National
Comprehensive
Cancer
Network®

NCCN Guidelines Version 1.2025 Prostate Cancer

NCCN
I

Discussion

SYSTEMIC THERAPY FOR M1 CRPC: ADENOCARCINOMA^{f,fff,ggg,hhh,iii}

No prior docetaxel/no prior novel hormone therapy ⁱⁱⁱ	Progression on prior novel hormone therapy/no prior docetaxel ⁱⁱⁱ
- Preferred regimens - Abiraterone^{z,kkk} (category 1 if no visceral metastases) - Docetaxel^{ddd} (category 1) - Enzalutamide^z (category 1) - Useful in certain circumstances - Niraparib/abiraterone^{z,iii,mmm} for BRCA mutation (category 1) - Olaparib/abiraterone^{z,kkk,iii} for BRCA mutation (category 1) - Pembrolizumab for MSI-H/dMMR^{ddd} (category 2B) - Radium-223^{s,nnn} for symptomatic bone metastases (category 1) - Sipuleucel-T^{ddd,ooo} (category 1) - Talazoparib/enzalutamide for HRR mutation^{z,iii} (category 1) - Other recommended regimens - Other secondary hormone therapy^z	- Preferred regimens - Docetaxel (category 1)^{ddd} - Olaparib for BRCA mutationⁱⁱⁱ (category 1) - Rucaparib for BRCA mutationⁱⁱⁱ (category 1) - Useful in certain circumstances - Cabazitaxel/carboplatin^{ddd} - Niraparib/abiraterone^{z,iii,mmm} for BRCA mutation (category 2B) - Olaparib for HRR mutation other than BRCA1/2ⁱⁱⁱ - Pembrolizumab for MSI-H/dMMR or TMB ≥10 mut/Mb^{ddd} (category 2B) - Radium-223^{s,nnn} for symptomatic bone metastases (category 1) - Sipuleucel-T^{ddd,ooo} - Talazoparib/enzalutamide for HRR mutation^{z,iii} (category 2B) - Other recommended regimens - Other secondary hormone therapy^z
Progression on prior docetaxel/no prior novel hormone therapy ⁱⁱⁱ	Progression on prior docetaxel and a novel hormone therapy ⁱⁱⁱ
- Preferred regimens - Abiraterone^{z,kkk} (category 1) - Cabazitaxel^{ddd} - Enzalutamide^z (category 1) - Useful in certain circumstances - Cabazitaxel/carboplatin^{ddd} - Mitoxantrone for palliation in symptomatic patients who cannot tolerate other therapies^{ddd} - Niraparib/abiraterone^{z,iii,mmm} for BRCA mutation - Olaparib/abiraterone^{z,kkk,iii} for BRCA mutation - Pembrolizumab for MSI-H/dMMR^{ddd} (category 2B) - Radium-223^{s,nnn} for symptomatic bone metastases (category 1) - Sipuleucel-T^{ddd,ooo} - Talazoparib/enzalutamide for HRR mutation^{z,iii} - Other recommended regimens - Other secondary hormone therapy^z	- Preferred regimens - Cabazitaxel^{ddd} (category 1) - Docetaxel rechallenge^{ddd} - Useful in certain circumstances - Cabazitaxel/carboplatin^{ddd} - Lutetium Lu 177 vipivotide tetraxetan (Lu-177-PSMA-617) for PSMA-positive metastases^{ppp} (category 1) - Mitoxantrone for palliation in symptomatic patients who cannot tolerate other therapies^{ddd} - Olaparib for HRR mutationⁱⁱⁱ (category 1 for BRCA mutation) - Pembrolizumab for MSI-H/dMMR, or TMB ≥10 mut/Mb^{ddd} - Radium-223^{s,nnn} for symptomatic bone metastases (category 1) - Rucaparib for BRCA mutationⁱⁱⁱ - Other recommended regimens - Other secondary hormone therapy^z

NCCN Categories of Evidence and Consensus

Category 1: Based upon high-level evidence (≥1 randomized phase 3 trials or high-quality, robust meta-analyses), there is uniform NCCN consensus (≥85% support of the Panel) that the intervention is appropriate.

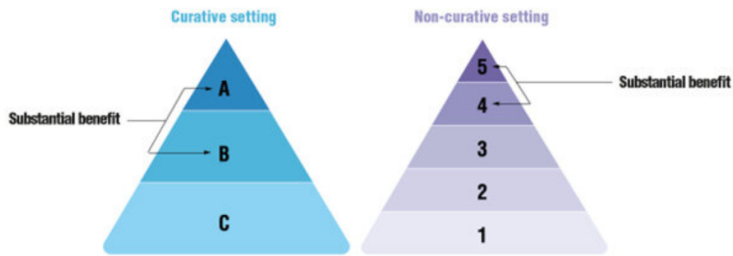
NCCN, national comprehensive cancer network, CRPC, castration-resistant prostate cancer;

PSMA, prostate-specific membrane antigen

ESMO-MCBS v2.0 consists of 6 evaluation forms and a Quality of Life (QoL) checklist.

Choosing which form to use depends on the information available in the peer reviewed publication of the clinical trial that led to the licensed indication of the treatment you are interested in. The type of study will dictate which evaluation form to use.

The highest possible grades of the ESMO-MCBS are A in the curative setting, and 5 for non-curative indications (for the primary-end point OS). Grades of A and B in the curative setting and 5 and 4 in the non-curative setting indicate substantial clinical benefit. New therapies demonstrating substantial clinical benefit justify rapid consideration for reimbursement.



5

Score

Pending data, score might change

Indication details

Combined Agent(s)	Best standard of care (restricted)
Control Arm	Best standard of care (restricted)
EMA Therapeutic Indication	177Lu-PSMA-617 in combination with androgen deprivation therapy (ADT) with or without androgen receptor (AR) pathway inhibition is indicated for the treatment of adult patients with progressive prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with AR pathway inhibition and taxane based chemotherapy.
FDA Therapeutic Indication	177Lu-PSMA-617 for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy.
Tumour Type	Genitourinary cancers
Tumour Sub-type	Prostate cancer
Tumour Stage	Metastatic
Tumour Sub-group	PSMA+ (mCRPC)
Trial name	VISION
NCT Number	NCT03511664
Trial Phase	Phase III

177Lu-PSMA-617VISION

PRELIMINARY SCORE

CURATIVE

ANNOTATION

AT - Acute toxicityPT - Persistent toxicity

NON-CURATIVE

OS

ADJUSTMENTS

Quality of life

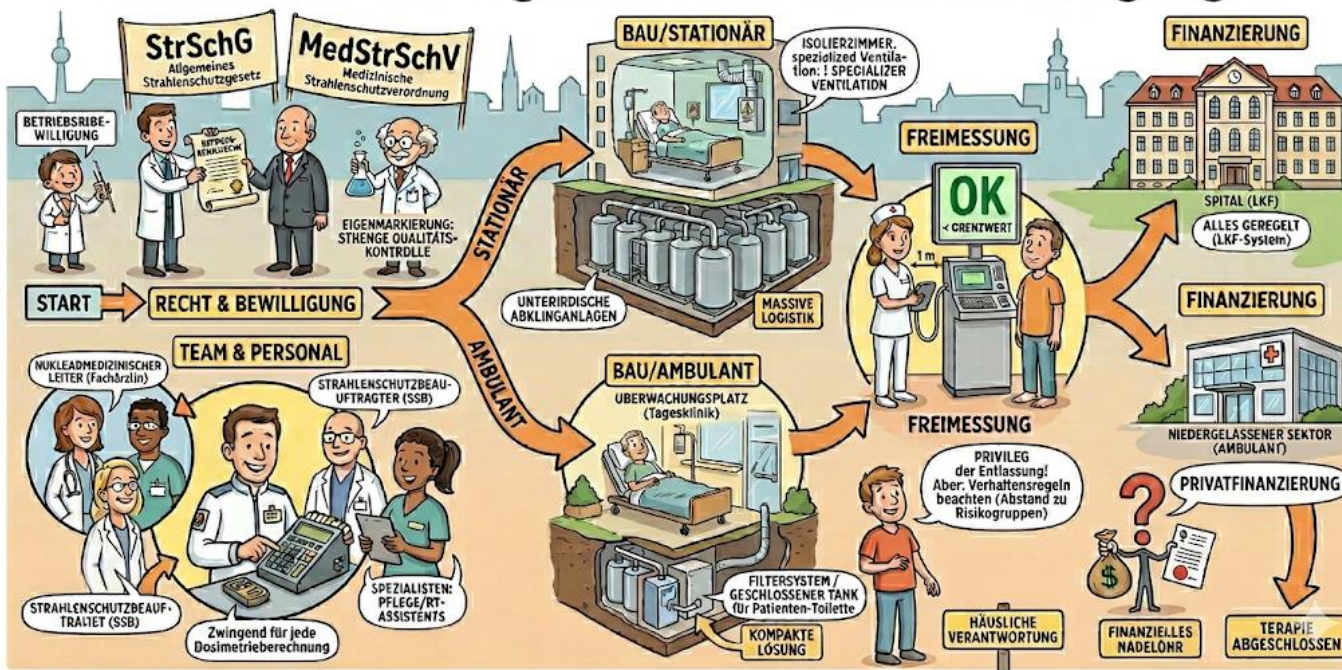
Improved QoL

Serious and disabling adverse effects

Herausforderungen der PSMA RLT



Strukturelle und regulatorische Rahmenbedingungen



*Nuklearmedizin/Radiologie/(Uro)onkologie/Strahlentherapie/Pathologie

- Die PSMA RLT: Evidenz-basierte Therapieoption für Patienten mit metastasierten Prostatakarzinom
- sehr gut verträglich, einfach zu applizieren und nebenwirkungsarm

Herausforderungen:

- interdisziplinäres Setting (Tumorboard, Med.Physik, Pflege und Radiotechnologen)
- Theranostisches Konzept -> PET/CT Bildgebung
- RLT in Österreich nicht breit verfügbar (nur wenige Zentren in Ö → uneinheitlicher Patientenzugang)
- Umgang mit Radioaktivität (Strahlenschutz) rechtlich föderal unterschiedlich geregelt
- Unklare Finanzierung der verschiedenen Settings stationär(MEL vorhanden)/tagesstationär/ambulant