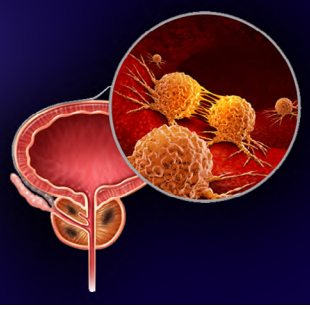
Prostate Cancer Practice Review™



Making Education Easy

Issue 32 - 2026

In this issue:

Abbreviations used in this issue:

ADT = androgen deprivation therapy; **AR** = androgen receptor; **ARPI** = androgen receptor pathway inhibitor; **CT** = computerised tomography; **FDA** = US Food & Drug Administration; **HRR** = homologous recombination repair; **Lu-PSMA** = lutetium prostate-specific membrane antigen; **mCRPC** = metastatic castration-resistant prostate cancer; **mCSPC** = metastatic castration-sensitive prostate cancer; **mHNPC** = metastatic hormone-naïve prostate cancer; **mPC** = metastatic prostate cancer; **MRI** = magnetic resonance imaging; **NCCN** = US National Comprehensive Cancer Network; **nmCRPC** = non-metastatic castration-resistant prostate cancer; **PARP** = poly(ADP-ribose) polymerase; **PC** = prostate cancer; **PBS** = Pharmaceutical Benefits Scheme; **PET** = positron emission tomography; **PSA** = prostate-specific antigen; **RCT** = randomised clinical trial.

Earn CPD

Royal Australasian College of Physicians (RACP) MyCPD participants can claim the time spent reading and evaluating research reviews as CPD in the online MyCPD program. Please contact MyCPD@racp.edu.au for any assistance.

Royal Australian & New Zealand College of Radiologists (RANZCR) members can claim reading related to their practice as a CPD activity under the category 'journal reading and web based no certificate *reflection required'. More info.

Nursing and Midwifery Board of Australia (NMBA) Journal reading and watching videos (including Research Reviews') may be considered a self-directed activity set out in the NMBA Registration Standard: Continuing Professional Development. One hour of active learning will equal one hour of CPD. Details at NMBA CPD page.

Welcome to the 32nd issue of Prostate Cancer Practice Review.

This Review covers news and issues relevant to clinical practice in prostate cancer. It brings you the latest updates, both locally and from around the globe, in relation to topics, such as new and updated treatment guidelines, changes to medicines reimbursement and licensing, educational, professional body news, and more. Finally, on the back cover you will find a summary of upcoming local and international educational opportunities including workshops, webinars and conferences.

We hope you enjoy this Research Review publication and look forward to hearing your comments and feedback.

Kind Regards,

Dr Janette Tenne
Editor
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Clinical Practice

NCCN prostate cancer update (version 2.2026/3.2026)

Recent National Comprehensive Cancer Network (NCCN) PC guideline updates (2026 iterations) consolidate mPC treatment pathways.

"The Guidelines sections included in this article focus on…mCSPC, nmCRPC…and mCRPC. For patients with mCSPC, disease characteristics, such as whether metastases arose synchronously or metachronously and the degree of metastatic burden, impact therapy decisions, including how much treatment intensification is appropriate and when prostate-directed and/or metastasis-directed therapy should be considered. In the mCRPC setting, androgen deprivation therapy is continued with the sequential or concurrent addition of certain androgen receptor pathway inhibitors, chemotherapies, immunotherapies, radiopharmaceuticals, and/or targeted therapies."

Australian/NZ clinicians will note the increasing operationalisation of "prior therapy-driven" algorithms for mCRPC and the shift toward tool-supported navigation (NCCN Guidelines Navigator®) for point-of-care use.

The NCCN PC guideline update is here.

Kindly Supported by

Changes to the EAU prostate cancer guideline

For the European Association of Urology's (EAU) 2025 Prostate Cancer Guidelines update, new and relevant evidence was appraised through a literature review across all Guideline sections. Key updates to the EAU 2025 Prostate Cancer Guidelines are shown in **Table 1**.

Addition of Table 3.1: Definition of familial and hereditary PC
Update of the EAU risk groups for biochemical recurrence of localised and locally-advanced PC based on systematic biopsy. EAU intermediate-risk group has now been split into favourable and unfavourable.
Addition of Table 5.3: Sources of error in PSA value assessment
Significant update to section 5.4.2.4 – MRI in population-based screening protocols
Adaption of the recommendation for transperineal biopsy in section 5.6.4
Restructure and update of section 5.5.2.6 Surgical techniques for N-staging
Updated recommendation for use of prostate-specific antigen-PET/CT for staging of intermediate-risk PC (section 5.8.5)
General recommendations for management of PC have been removed. All recommendations are now given per disease stage.
Section 6.6.4 – Combination therapies for management of metastatic PC has been restructured
New recommendation on use of darolutamide in section 6.6.8 – Recommendations for the first-line treatment of mHSPC
New recommendation on discussing all patients with mHSPC in a multidisciplinary team in section 6.6.9 – Recommendations for the first-line treatment of mHSPC
New recommendation on offering bone protective agents to men on long-term ADT plus/minus ARPI in the supportive care recommendations in section 6.6.9 related to mHSPC
New recommendation in section 7.4.6 for follow-up during hormonal treatment
Expansion and update of section 8.2.5 – ADT with section 8 – Quality of life outcomes in PC

Table 1. Summary of 2025 changes to the European Association of Urology's (EAU) 2025 Prostate Cancer Guidelines.

Read the 2025 EAU guideline update for PC here.

PCFA submission to NHMRC: 2025 guidelines for early detection of PC

"Prostate Cancer Foundation of Australia (PCFA) is seeking approval under section 14A of the National Health and Medical Research Council Act 1992 for the DRAFT 2025 Clinical Guidelines for the Early Detection of Prostate Cancer.

The 2025 Guidelines are designed to supersede the 2016 Clinical Practice Guidelines for PSA Testing, recognising that significant advancements in diagnosis and treatment have created an evidence-based pathway for a more structured testing program."

These drafted recommendations are a shift toward structured, risk-adapted early detection of PC in Australia, replacing previous discretionary PSA testing advice, and emphasising individualised decision-making and prioritisation of high-risk groups (**Table 2**).

Risk Assessment and Priority Populations • Defines higher-risk males (significant family history, Black males of sub-Saharan African ancestry, confirmed *BRCA2* gene mutations) with strong and conditional recommendations on risk stratification • Prioritises development of culturally appropriate education campaigns and supports for Aboriginal and Torres Strait Islander males and other vulnerable groups
Decision Support • Recommends structured decision support to inform men about benefits and harms of testing, incorporating personal values and circumstances, with options like written information and decision aids
Early Detection and PSA Testing • Recommends initiating conversations about PSA testing in males aged ≥50 years in primary care and considering individualised testing discussions for males aged 40-49 years • Strong recommendation for offering PSA testing every 2 years for males aged 50-69 years • For higher-risk males, PSA testing suggested every 2 years from age 40 • Recommends PSA testing for males aged ≥70 years on a case-by-case basis, with clinical assessment informing ongoing testing • Suggests PSA testing only in individuals with life expectancy >7 years
Digital Rectal Examination (DRE) • Strong conditional recommendation against routine DRE in primary care alongside PSA testing, while noting its role in specialist assessment
Diagnostic Pathways • Multiparametric MRI (mpMRI) is recommended as the first diagnostic step for elevated PSA before biopsy • Conditional recommendations on prostate biopsy pathways based on mpMRI findings and PSA density thresholds • Inclusion of PSMA PET/CT and targeted biopsy options where appropriate
Implementation Tools • Flowcharts provided for clinical pathways covering PSA testing by age group (40-49, 50-69, ≥70 years), risk stratification, and priority population considerations

Table 2. Summary of changes in Prostate Cancer Foundation of Australia's (PCFA) draft 2025 clinical guidelines for the early detection of prostate cancer.

View the summary of recommendations here.

Regulatory News

Pluvicto® Australian approval documentation published

Few effective therapeutic options are available for patients with mCRPC who have previously been treated with an ARPI and taxane-based chemotherapy, reinforcing an unmet medical need for additional effective treatment strategies in this setting.

In November 2025, a regulatory milestone was achieved in Australia with the publication of the Australian Public Assessment Report (AusPAR)/product information (PI) materials for Pluvicto® (lutetium [^{177}Lu] vipivotide tetraxetan; Novartis Pharmaceuticals Australia Pty Ltd).

Based on a review of quality, safety, and efficacy, the Therapeutic Good's Association (TGA) decided to register Pluvicto® 1,000 MBq/mL, solution for injection, vial indicated for:

- Pluvicto® is indicated for the treatment of adult patients with PSMA-positive mCRPC who have been treated with AR pathway inhibition and taxane-based chemotherapy.

Read the AusPAR report on Pluvicto® here; the Pluvicto® PI (July 2025) is here.

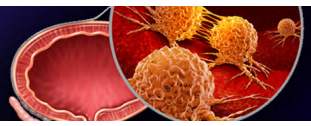
Section 19a approval for Illuccix® (ga-68 gozetotide) supply pathway

A Section 19A approval was published in November 2025 by the TGA for Illuccix® (gozetotide; Telix Pharmaceuticals [ANZ] Pty Ltd) kits for radiopharmaceutical preparation (Eckert & Ziegler GalliaPharm Ge 68/Ga-68 generator [UK]), specifically supporting PET/CT imaging in PC (initial staging in those at risk of metastasis and evaluation of suspected recurrence with rising PSA). While Illuccix® has long-standing registration, the 19A mechanism is relevant to services managing tracer availability and supply continuity, particularly where local production/import constraints can affect access. From 19 August 2025, Illuccix® was in short supply in Australia. This supply issue was resolved on 8 January 2026.

Illuccix® is indicated for use in patients with PC:

- Who are at risk of metastasis and who are suitable for initial definitive therapy
- Who have suspected recurrence based on elevated serum-PSA level
- For the selection of patients with mPC in whom lutetium ^{177}Lu vipivotide tetraxetan PSMA-directed therapy is indicated

Read the Section 19A approval statement on Illuccix® here; the Illuccix® PI (January 2025) is here.



FDA approval of Rubraca® (rucaparib) for BRCA-mutated mCRPC

In December 2025, the FDA granted regular approval (not accelerated) to rucaparib (Rubraca®, pharmaand GmbH) for adults with deleterious *BRCA* mutation-associated (*BRCAm*) mCRPC previously treated with an AR-directed therapy, with patient selection through an FDA-approved companion diagnostic. This is a notable "signal" update for global practice, as it reinforces the durability of PARP-inhibitor positioning in biomarker-selected mCRPC, and could influence comparative guideline language and payer deliberations beyond the US.

Efficacy was evaluated in TRITON3 (NCT02975934), a randomised, open-label confirmatory trial supporting the FDA 2020 accelerated approval of rucaparib. TRITON3 enrolled 405 patients with mCRPC who had progressed on a prior AR pathway inhibitor and had not received chemotherapy in the castration-resistant setting; 302 patients had *BRCAm* and 103 had ATM mutations (*ATMm*). Patients were randomised 2:1 to rucaparib or physician's choice of enzalutamide, abiraterone acetate, or docetaxel, with continued ADT. The primary endpoint was independently assessed radiographic progression-free survival (rPFS).

Rucaparib significantly improved rPFS versus physician's choice in patients with *BRCAm* (median 11.2 versus 6.4 months; hazard ratio [HR] 0.50; p<0.0001) and in the overall population, with no statistically significant overall survival (OS) benefit. Exploratory analyses showed no rPFS or OS benefit in patients with *ATMm*, potentially showing that the treatment effect was driven by the *BRCAm* subgroup.

Prescribing information includes warnings for myelodysplastic syndrome/acute myeloid leukaemia and embryo-foetal toxicity. The recommended dose is rucaparib 600 mg orally twice daily until disease progression or unacceptable toxicity. Full prescribing information for Rubraca® will be posted on Drugs@FDA.

The FDA approval statement is here.

Akeega® (niraparib + abiraterone) FDA expanded to BRCA2m mCSPC

On 12 December 2025, the FDA approved niraparib + abiraterone acetate (Akeega®, Janssen Biotech, Inc.) with prednisone for adults with deleterious/suspected deleterious *BRCA2m* mCSPC, as determined by an FDA-approved test. This approval represents a major shift: PARP-inhibitor-based precision therapy is moving earlier in the hormone-sensitive metastatic setting, which has downstream implications for sequencing, what remains available at mCRPC, and how countries like Australia or New Zealand evaluate clinical and economic value.

Efficacy was evaluated in AMPLITUDE (NCT04497844), a double-blind, phase 3 RCT that enrolled 696 patients with mCSPC harbouring homologous recombination repair gene mutations (*HRRm* mCSPC). Patients were randomised 1:1 to receive niraparib in combination with abiraterone acetate + prednisone (AAP), or placebo + AAP (all participants continued background ADT).

Niraparib + AAP showed a statistically significant improvement in rPFS (primary endpoint) compared with placebo + AAP in the *HRRm* population.

In an exploratory subgroup analysis of 323 patients with *BRCA2m* disease, the HR for rPFS was 0.46 (95% CI 0.32-0.66), with median rPFS not estimable (95% CI 41 months to not estimable) in the niraparib + AAP arm versus 26 months (95% CI 18-28) in the placebo + AAP arm. In contrast, in 373 patients with non-*BRCA2 HRRm*, the HR for rPFS was 0.88 (95% CI 0.63-1.24), indicating that the overall treatment effect was driven by patients with *BRCA2m*. At the first interim OS (secondary endpoint) analysis, 91 deaths occurred in the *BRCA2m* subgroup, including 36 (22%) for niraparib + AAP, and 55 (34%) for placebo + AAP.

The US PI includes warnings and precautions for myelodysplastic syndrome/acute myeloid leukaemia, myelosuppression, hypokalaemia, fluid retention and cardiovascular adverse reactions, hepatotoxicity, adrenocortical insufficiency, hypoglycaemia, increased fracture risk and mortality when used in combination with radium Ra223 dichloride, posterior reversible encephalopathy syndrome, and embryo-foetal toxicity.

The recommended regimen is niraparib 200 mg and abiraterone acetate 1,000 mg administered orally once daily with prednisone 5 mg once daily until disease progression or unacceptable toxicity. Patients should receive concurrent gonadotropin-releasing hormone (GnRH) analog therapy or have undergone bilateral orchiectomy.

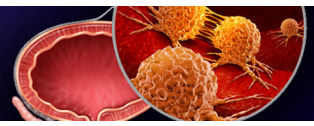
Full prescribing information for Akeega® will be posted on Drugs@FDA.

News in Brief

"World-first" Australian trial press release: New combination for advanced PC

PCFA reported world-first findings from the Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP) clinical trial EVOLUTION, suggesting that ^{177}Lu-PSMA with nivolumab and ipilimumab can slow the spread of PC more effectively than Lu-PSMA alone. As this release outlines emerging combination strategies that could enter conference programs, future guideline deliberations, or trial replication/extension across Australian centres, it is relevant for Australian clinicians and services.

More information can be found about the release here.



Update on current prostate cancer clinical trials

Ongoing PC clinical trials led by the ANZUP are shown in **Table 3**.

Clinical trials in recruitment
ANZadapt NSW I VIC I QLD I SA I WA Phase 2 RCT of patient-specific adaptive versus continuous abiraterone or enzalutamide for mCRPC
DARO-LIPID NSW I VIC Phase 2 RCT of sphingosine kinase inhibitor (opaganib) in addition to darolutamide for poor prognostic mCRPC based on a companion circulating lipid biomarker, PCPro
GenI-AIRSPACE VIC I QLD I SA Evaluating the impact of genomic testing on treatment decison-making in men with favourable intermediate risk PC suitable for radical treatment and active surveillance
WOMBAT NSW I VIC I QLD I SA Investigates if bipolar ADT can prolong time for nmCRPC to become detectable in other bodily areas
NINJA NSW I VIC I QLD I SA I WA I NZ Novel integration of new prostate radiation therapy schedules with adjuvant androgen deprivation
Clinical trials in follow up
DASL-HiCAP NSW I VIC I QLD I SA I WA I NZ I Ireland I Canada I USA Investigates if darolutamide, combined with the current best treatments, can improve outcomes for high-risk localised PC
ENAZA-p NSW I VIC I QLD I SA I WA Phase 2 RCT using PSMA as a therapeutic agent and prognostic indicator for mCRPC treated with enzalutamide
ENZARAD NSW I VIC I QLD I SA I WA I TAS I NZ I UK I Ireland I Belgium I Spain I Austria I Slovenia I USA Phase 3 RCT evaluating enzalutamide in first-line ADT for mPC
EVOLUTION NSW I VIC I SA I WA Phase 2 RCT of radionuclide ^{177}Lu-PSMA therapy versus ^{177}Lu-PSMA in combination with ipilimumab and nivolumab for mCRPC
proPSMA NSW I VIC I QLD I SA I WA Prospective RCT of Ga-68 PSMA-PET/CT imaging for staging high-risk PC prior to curative-intent surgery or radiotherapy
TheraP NSW I VIC I QLD I SA I WA Phase 2 RCT of ^{177}Lu-PSMA theranostic versus cabazitaxel in progressive mCRPC
#UpFrontPSMA NSW I VIC I QLD I SA I WA Phase 2 RCT of sequential ^{177}Lu-PSMA and docetaxel versus docetaxel in mHNPC

Table 3. Ongoing prostate cancer clinical trials led by the Australian and New Zealand Urogenital and Prostate Cancer Trials Group (ANZUP).

Find more information on these trials on the ANZUP clinical trials page, here.

Heading to ASCO 2026?

For planning and abstract-tracking at the 2026 ASCO GU in San Fransico, USA, the published "Dates to Know" note that registration/housing opened in **October 2025**, with an early registration deadline of **January 21, 2026** (ET).

Read more on ASCO 2026's Dates to Know, here.

PBS general copayment cap change, effective 1 January 2026

The 1 January 2026 PBS settings, including the general patient maximum charge referenced in the PBS explanatory notes, are routinely leveraged in PC supportive-care planning, as many patients with PC require multiple, continuous medicines. When combined with the Safety Net, these settings could shape counselling on expected annual out-of-pocket costs, which is potentially relevant for men with PC on long-duration ADT, ARPIs, or bone health medications.

For more on the PBS general co-payment cap change, click here.

Conferences, Workshops, and CPD

Please click on the links below for upcoming local and international prostate cancer meetings, workshops and CPD.

AUA - Meetings & Education
COSA – Events
MOGA – Events
USANZ – Events

Research Review Publications

Genitourinary Cancer Research Review with Associate Professor Andrew Weickhardt

Prostate Cancer Research Review with Professor Niall Corcoran

Urology Research Review with Professor Eric Chung

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