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Access to Modern Therapies for Prostate Cancer Patients in Central and Eastern Europe (CEE): A Cross-country Assessment of HTA and Reimbursement Pathways

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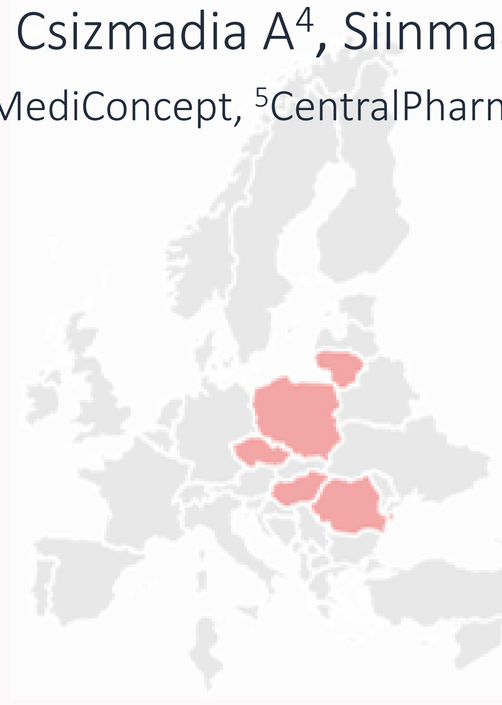
Background and Objective

- Prostate cancer (PC) is the most diagnosed cancer among men in 118 countries, with over 86,200 cases and 26,700 deaths annually in Central and Eastern Europe (CEE).
- Modern therapies for PC include nonsteroidal second-generation androgen receptor inhibitors (ARPI), targeted therapies such as poly(ADP-ribose) polymerase (PARP) inhibitors or radioligand therapies, and combined products.
- This research assesses the availability and market access conditions of these modern PC therapies in selected CEE countries.



Methods

- We conducted a targeted review of reimbursement and access conditions of modern PC therapies in Poland, Czechia, Hungary, Lithuania, and Romania, based on data available as of February 2026.
- We also reviewed country-specific pricing and reimbursement frameworks for oncology drugs.

Results

- Poland and Lithuania offer the widest range of reimbursed modern therapies (ARPI, PARP inhibitors, radioligands) and are progressing through advanced price negotiations for ^{177}Lu vipivotide tetraxetan. In contrast, Hungary remains in a transitional phase with several key drugs awaiting decisions (Table 1).
- All analyzed countries use a 100% reimbursement model via specialized drug programs, positive lists or confidential managed entry agreements (MEAs) (Table 2).
- Across the region, market access is governed by mandatory Health Technology Assessment (HTA) reports and the strategic use of risk-sharing agreements to manage high innovation costs (Table 2).
- Significant discrepancies between statutory timelines and real-world implementation exist; the Czech Republic and Poland offer the most efficient paths (~10-12 months), while processes in Romania and Lithuania can reach 24 months due to prolonged post-decision price and Managed Entry Agreement (MEA) negotiations (Table 2).

Table 1: Overview of availability of modern therapies for PC in 5 CEE countries (as of February 2026)

		Czechia	Hungary	Lithuania	Poland	Romania
Modern therapies reimbursed for PC						
ARPI:	• Abiraterone	Reimbursed	Reimbursed	Reimbursed	Reimbursed	Reimbursed
	• Apalutamide	Reimbursed	Reimbursed	Reimbursed	Reimbursed	Reimbursed
	• Darolutamide	Reimbursed	Not reimbursed	Reimbursed	Reimbursed	Reimbursed
	• Enzalutamide	Reimbursed	Reimbursed	Reimbursed	Reimbursed	Reimbursed
PARP inhibitors:	• Olaparib	Reimbursed	Not reimbursed	Reimbursed	Reimbursed	Reimbursed
	• Talazoparib	Reimbursed	Not reimbursed	Not reimbursed	Reimbursed	Reimbursed
Combination: Niraparib + abiraterone		Not reimbursed	Not reimbursed	Reimbursed	Reimbursed	Not reimbursed
Radioligand therapy: ^{223}Ra dichloride		Not reimbursed	Reimbursed	Reimbursed	Reimbursed	Not reimbursed
What's next?		No major upcoming therapies; Generic enzalutamide expected	3 therapies (darolutamide, olaparib, niraparib + abiraterone) awaiting reimbursement	^{177}Lu price negotiations Talazoparib not yet assessed	^{177}Lu awaiting reimbursement; Generic enzalutamide expected	^{177}Lu and niraparib + abiraterone awaiting reimbursement

Reimbursed Not reimbursed

Table 2: Access conditions of modern PC therapies in 5 CEE countries (as of February 2026)

	Czechia	Hungary	Lithuania	Poland	Romania
Time to reimbursement	**~10–12 mo** *from P&R dossier submission*	**90–180 days** *from P&R dossier submission, set by law* RSA or required legislative amendments may extend timeline; ~7 mo–3 yrs real-world	**≤180 days** *formal procedural limit* Up to ~2 yrs real-world	**180–240 days** *formal* 318 days 2024 average real-world	**18–24 mo** *total typical timeline* MEA: + 12-18 mo
Stakeholders	SÚKL MoH + payers	NEAK HTA Division	MoH / Reimbursement Committee SMCA	MoH / AOTMiT	MoH + CNAS ANMDMR
HTA requirements	Clinical + CEA + BIA + access impact	Clinical + economic evidence + BIA; KOL input routine	Clinical / comparator relevance + CEA/CMA + BIA; KOL input recommended, not mandatory	Clinical + CEA + BIA + comparator alignment	Scorecard (driven by HTA outcomes and EU reimbursement status) + BIA; no full local CEA
Reimbursement conditions	Almost all PC therapies partially reimbursed; no indication-specific codes required	100% reimbursement; Hospital reimbursement for chemotherapy; Specific indication codes, financing protocols	100% reimbursement; No distinct indication codes beyond positive-list entry	100% reimbursement via chemotherapy catalogue or drug program	100% reimbursement (National Oncology Program); Protocol-restricted prescribing; indication codes required for cost-volume indications
MEA / RSA	Confidential, required with all 7 funds; common discounts, budget caps, patient-cap agreements	Common for high-impact oncology; success depends on RSA feasibility	Confidential RSA common for high-cost medicines	Possible confidential RSA for high-cost therapies (e.g., payback, capping, discounts)	Cost-volume and cost-volume-result agreements key for high-cost/innovative medicines; confidential, requirement for conditional HTA inclusion
Oncology pathway	Standard pathway; conditional or temporary pathways common for highly innovative therapies	Standard pathway; access/funding shaped by HTA outcome & RSA terms	Inclusion on positive reimbursement list; high-impact drugs face RSA requirements & extended timelines	Standard pathway or drug programs; MEAs commonly shape final access	Conditional HTA decisions common for oncology; manufacturer negotiates MEA with CNAS

Conclusions

- Access to modern PC therapies varies across CEE in therapeutic breadth and administrative efficiency. While leading markets provide comprehensive portfolios, others face delays driven by financial constraints and complex risk-sharing negotiations.
- Consistent with literature showing a vast reimbursement gap (64% in Czechia vs. 19% in Slovakia), systemic resource limits and administrative reality gaps result in persistent regional inequalities regarding the timely availability of patient access.

Abbreviations

AOTMiT, Agency for Health Technology Assessment in Poland; ANMDMR, National Agency for Medicines and Medical Devices in Romania; ARPI, Androgen Receptor Pathway Inhibitor; BIA, Budget Impact Analysis; CEA, Cost-Effectiveness Analysis; CEE, Central and Eastern Europe; CMA, Cost-Minimization Analysis; CNAS, Romanian National Health Insurance House; EMA, European Medicines Agency; HTA, Health Technology Assessment; KOL, Key Opinion Leader; MEA, Managed Entry Agreement; MoH, Ministry of Health; NEAK, Hungarian National Health Insurance Fund Administration; P&R, Pricing and Reimbursement; PARP, Poly(ADP-ribose) Polymerase; PC, Prostate Cancer; RSA, Risk-Sharing Agreement; SMCA, State Medicines Control Agency in Lithuania; SÚKL, State Institute for Drug Control in Czechia

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