Budget Impact Analysis of ^{68}Ga-PSMA-11 PET/CT Imaging Followed by ^{177}Lu-PSMA-617 Therapy in Metastatic Castrate Resistant Prostate Cancer

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INTRODUCTION

- Metastatic Castration Resistant Prostate Cancer (mCRPC) is a significant clinical challenge with poor prognosis, affecting over 90,000 men and accounting for over 3,000 cancer-related deaths annually in Australia[1]
- Clinical evidence supports the theranostic approach of using ^{68}Ga-PSMA-11 PET/CT imaging to identify suitable candidates for prostate-specific membrane antigen (PSMA) targeted radioligand therapy and to enable accurate assessment of treatment response[2]
- A budget impact analysis (BIA) was conducted from an Australian healthcare perspective to estimate total healthcare expenditures of introducing ^{68}Ga-PSMA-11 PET/CT imaging followed by ^{177}Lu-PSMA-617 radioligand therapy for patients with mCRPC in Australia

METHOD

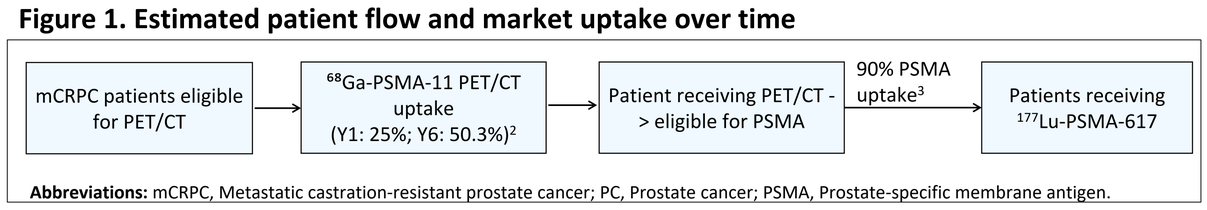
Population: Patients eligible for ^{68}Ga-PSMA-11 PET/CT imaging were estimated using prostate cancer mortality data derived from Cancer Australia[2]. An annual growth rate of **1.4%** was then applied across a 6-year time horizon to account for population change over a span of six years[3] **(Figure 1).** The uptake rate of ^{68}Ga-PSMA-11 PET/CT was based on clinical expert input and 1686 Public Summary Document (PSD), with **15%** relative increase in annual uptake rate[4] **(Figure 1)**

Costs: The model incorporated direct medical costs associated with diagnostics, drug acquisition, administration, and subsequent treatment. Unit cost data were obtained from the Medical Services Advisory Committee (MSAC) listings- the Pharmaceutical Benefits Scheme (PBS), and Medicare Benefits Schedule (MBS). All costs were reported in Australian dollar **(Table 1)**

Treatment duration: The mean number of treatment cycles were derived from a cost-effectiveness model[11]. Patients eligible for cabazitaxel received an average of 4.17 cycles of ^{177}Lu-PSMA-617, while those on BSC received 4.82 cycles. The mean number of treatment cycle of cabazitaxel was 6.70

Subsequent therapy: Patient progression in the model is based on data from the TheraP[5] and VISION[6] trials. Following progression on initial therapy, **14.9%** of patients were assumed to transition to subsequent lines of treatment (based on 1686 PSD)[4]. The distribution of therapies, and treatment durations were derived from published clinical data or internal assumptions **(Table 2)**

Figure 1. Estimated patient flow and market uptake over time



Abbreviations: mCRPC, Metastatic castration-resistant prostate cancer; PC, Prostate cancer; PSMA, Prostate-specific membrane antigen.

Table 1. Unit cost inputs used in the model

Category	Cost inputs	Values
Diagnostic cost	Cost of ^{68}Ga-PSMA-11 PET/CT imaging (61563/64)	$1,300.00[7]
Drug therapy cost	Cost of ^{177}Lu PSMA 617 per cycle	$8,000.00[4]
Other drug costs	Cost of cabazitaxel (per 3 weeks) (4376H)	$272.95[8]
	Cost of docetaxel (per 3 weeks) (7236W)	$151.92[8]
Administration costs	Administration cost of IV cabazitaxel (13950)	$118.30[7]
	Administration cost of IV docetaxel (13950)	$118.30[7]

Abbreviations: CT, Computed tomography, IV, Intravenous; PET, Positron emission tomography; PSMA, Prostate-specific membrane antigen.

Table 2. Duration and assumptions for subsequent therapy use after progression

Average duration of subsequent therapy (months)		Distribution of subsequent therapy		
		^{177}Lu PSMA 617	Cabazitaxel	BSC
Cabazitaxel	5.05[9]	50%	0%	50%
Docetaxel	6.60[10]	50%	100%	50%

Abbreviations: BSC, Best supportive care; PSMA, Prostate-specific membrane antigen

RESULTS

Estimated Eligible Population

The eligible population for imaging was projected to increase from **3,853** in Year 1 to **4,134** in Year 6. Based on the modeled uptake rates, the number of patients undergoing PSMA PET imaging is projected to increase from 963 in Year 1 to 2,079 in Year 6. Based on 1686 PSD, 90% of these patients receive ^{177}Lu-PSMA-617. It was assumed that 25% of these were eligible for cabazitaxel, while the remaining 75% received best supportive care (BSC). The financial implications were modelled within the theranostic treatment pathway **(Table 3)**

Financial Implications

With ^{68}Ga-PSMA-11 PET/CT:

- The estimated cost to the MBS for diagnostic imaging is **AUD 1.2M** in Year 1, increasing to **AUD 2.7M** in Year 6, consistent with uptake growth over time
- The MBS cost for ^{177}Lu-PSMA-617 therapy is estimated to increase from **AUD 32M** to **AUD 69M** across the six-year horizon
- The total cost to government (including subsequent treatment cost) is estimated at **AUD 33.4M** in Year 1, increasing to **AUD 72.2M** by Year 6 **(Table 3)**

Without ^{68}Ga-PSMA-11 PET/CT:

- The cost to MBS (includes administration cost of cabazitaxel) is estimated at **AUD 0.1M in Year 1**, increasing to **AUD 0.3M in Year 6**
- A higher subsequent treatment cost is expected in this scenario without PSMA, which increases from **AUD 0.3M** in Year 1 to **AUD 0.7M** in Year 6
- The total cost to government is estimated at **AUD 0.8M** in Year 1, increasing to **AUD 1.8M** in Year 6 **(Table 4)**

Net Impact:

Table 5 summarizes the net financial implication of introducing PSMA theranostic approach. While this approach increases upfront costs, it is offset by improved clinical outcomes and more efficient patient selection, potentially reducing long-term treatment costs and the need for subsequent therapies

Table 3. Financial implications when ^{68}Ga-PSMA-11 PET/CT and ^{177}Lu-PSMA-617 is funded

Parameter	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Patients eligible for imaging	3,853	3,908	3,963	4,019	4,076	4,134
Uptake rate	25.0%	28.8%	33.1%	38.0%	43.7%	50.3%
Patients undergoing PSMA PET	963	1125	1312	1527	1781	2079
Cost to MBS (PSMA PET)[a]	**$1,234,171**	**$1,441,925**	**$1,680,712**	**$1,956,879**	**$2,282,321**	**$2,664,271**
Patients receive ^{177}Lu-PSMA-617 (90%)	**867**	**1013**	**1181**	**1375**	**1603**	**1871**
Cost to MBS (^{177}Lu-PSMA-617)	$31,915,053	$37,287,484	$43,462,393	$50,603,934	$59,019,722	$68,896,752
Cost of subsequent t/t[b]	$217,797	$312,568	$385,138	$456,998	$536,707	$628,359
Cost to government	**$33,367,021**	**$39,041,977**	**$45,528,243**	**$53,017,811**	**$61,838,750**	**$72,189,382**

[a] Greatest permissible gap at $98.70 -> cost of CT scan (applying 85% rebate + additional $5 for the Multiple Services Rule in the DIST) -> $1281.30
[b] Includes cost to the PBS and MBS for subsequent t/t (a 50/50 split of cabazitaxel or docetaxel was applied for subsequent t/t)
Abbreviations: MBS, Medicare Benefits Scheme; PSMA, Prostate-specific membrane antigen; PBS, Pharmaceutical Benefits Scheme; t/t, treatment.

Table 4. Financial implications when ^{68}Ga-PSMA-11 PET/CT and ^{177}Lu-PSMA-617 is not funded

Proposed therapy	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Patients on cabazitaxel (25%)	**217**	**253**	**295**	**344**	**401**	**468**
Cost to MBS (administration)[a]	$145,923	$170,487	$198,720	$231,373	$269,852	$315,012
Cost to PBS (minus co-pay)[b]	$376,609	$440,005	$512,871	$597,144	$696,453	$813,005
Cost of subsequent t/t[c]	$72,525	$88,568	$103,933	$121,209	$141,424	$165,110
Patients on BSC (75%)	**650**	**760**	**885**	**1031**	**1202**	**1404**
Cost of subsequent t/t[c]	$224,789	$272,980	$318,618	$371,024	$432,704	$505,099
Cost to government[d]	**$819,846**	**$972,040**	**$1,134,142**	**$1,320,750**	**$1,540,433**	**$1,798,226**

[a] IV administration cost of cabazitaxel ($100.56, 85% MBS rebate applied) per cycle (i.e., 6.60) is $673.31
[b] Cost of cabazitaxel per cycle is $272.95 -> cost of cabazitaxel per patient is $1827.67 (when mean treatment duration of a cycle is 6.70)
[c] 14.9% patients progress and receive subsequent therapy -> 100% patients receive docetaxel as subsequent t/t (includes PBS and MBS cost)
[d] Cost to MBS/PBS for drug acquisition in patient receiving BSC is $0, therefore only subsequent t/t cost is considered
Abbreviations: BSC, Best supportive care; IV, Intravenous; MBS, Medicare Benefits Scheme; PSMA, Prostate-Specific Membrane Antigen; PBS, Pharmaceutical Benefits Scheme; t/t, treatment.

Table 5. Net financial impact over six years

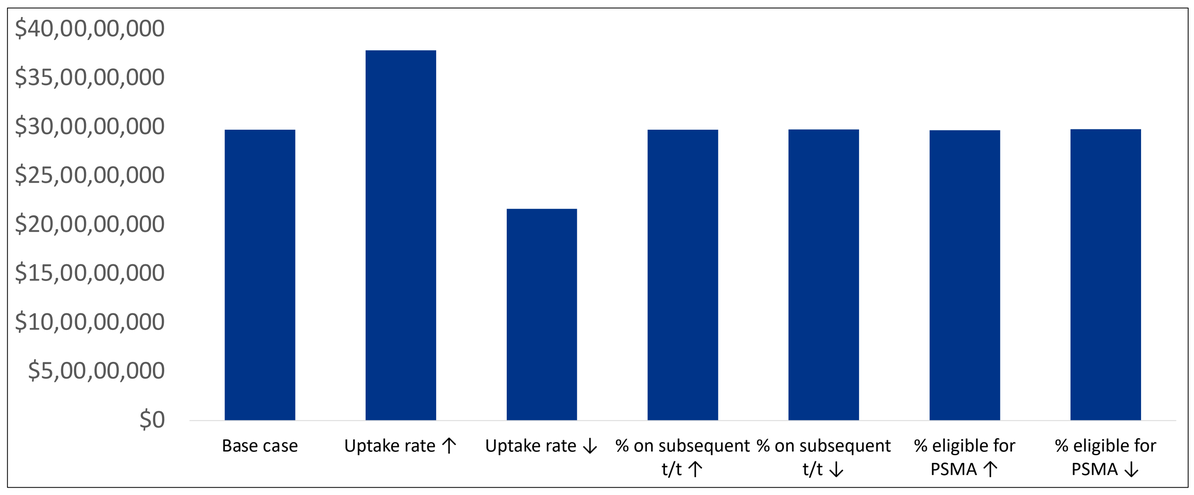
Net financial impact	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Cumulative
Cost to government (with PSMA)	$33,367,021	$39,041,977	$45,528,243	$53,017,811	$61,838,750	$72,189,382	$304,983,184
Cost to government (w/o PSMA)	$819,846	$972,040	$1,134,142	$1,320,750	$1,540,433	$1,798,226	$7,585,437
Net financial impact (diff)	**$32,547,175**	**$38,069,937**	**$44,394,101**	**$51,697,061**	**$60,298,317**	**$70,391,156**	**$297,397,747**

Abbreviations: Diff, Difference; PSMA, Prostate-specific membrane antigen; w/o, Without.

Scenario Analysis

Scenario analysis indicates that changes in the **uptake rate** are the primary drivers of cost variation, leading to the most significant increase or decrease in expenditure. Other parameters, contribute to relatively **minor cost shifts** compared to the base case **(Figure 2)**

Figure 2. Scenario-based variation (± 10%) in budget impact compared to base case



Abbreviations: PSMA, Prostate-specific membrane antigen; t/t, Treatment ↑: Increase ↓: Decrease

CONCLUSIONS

Introducing **^{68}Ga-PSMA-11 PET/CT** for mCRPC in Australia may involve upfront costs, but it offers significant clinical benefits. By accurately **identifying** patients suitable for radionuclide therapy, it enables earlier and more targeted treatment, improves quality of life, and avoids unnecessary exposure to costly and potentially ineffective therapies

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