

Australian Government

Cancer Australia

Strategy for Proton Beam Therapy for cancer patients in Australia

August 2023

Statement of Acknowledgement

Cancer Australia acknowledges Aboriginal and Torres Strait Islander people as the Traditional Custodians of Country throughout Australia. We pay our respects to Elders, past and present. We celebrate the ongoing connections of Aboriginal and Torres Strait Islander peoples to Country, culture, community, family and tradition and recognise these as integral to health, healing and wellbeing.

Cancer Australia acknowledges great diversity among Aboriginal and Torres Strait Islander peoples, and the contribution of the many voices, knowledge systems and experiences that guide all efforts to create a culturally safe and responsive cancer system that is equitable to all.

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Acknowledgments

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Cancer Australia gratefully acknowledges the support of the many individuals and groups who contributed to the development of this report, including a rapid review of the evidence delivered by the Sax Institute, and the members of the Proton Beam Therapy Strategic Planning Group.

See Appendices A and C for more information.

Executive summary

This report outlines a strategy for equitable access to Proton Beam Therapy (PBT) for cancer patients in Australia. Consideration of investment in PBT should be placed within a wider context of cancer treatment advancements, as well as the opportunity cost of over-investing in one technology at the expense of others.

PBT is not currently available in Australia. From 2015–16 to 2019–20, approximately seven patients per year have accessed PBT treatment overseas through the Commonwealth Government's Medical Treatment Overseas Program (MTOP). However, the annual demand for PBT in Australia has been estimated at 231 patients in 2021, increasing to 372 patients in 2025, 65.8% children and adolescent and young adults, and 34.2% adults.¹

The Australian Bragg Centre for Proton Therapy and Research (the Bragg Centre) in Adelaide is under construction and expected to commence operations in 2024-25. With an expected capacity of 750 patients per annum by 2031, the Bragg Centre will likely meet the demand for current MSAC-recommended indications, with some capacity for growth in additional non-MBS indications.

This Strategy was informed by jurisdictional policy and clinical representatives on the PBT Strategic Planning Group (PBT-SPG) and a clinically focussed PBT-SPG Working Group, and is underpinned by evidence, with an emphasis on service delivery that is patient-centred, culturally responsive, and provides equity of access.

The PBT-SPG highlighted the need for a networked approach to PBT delivery, including coordinated referral and treatment planning, an agreed national approach to data collection, and access to clinical trials as part of standard of care.

The Strategy was considered in the context of the Australian Cancer Plan (the Plan) which sets out a national reform agenda for the next 10 years, and the Plan implementation priorities to establish the Australian Comprehensive Cancer Network (ACCN) and the National Cancer Data Framework and Minimum Dataset to ensure nationally linked data across the cancer continuum.

The Strategy considers the following three options for the location and indicative timing for new PBT centres in Australia based on projected need, PBT capacity and equitable use:

- Option 1: One PBT machine per 26 million people in South Australia (SA), at the Australian Bragg Centre for Proton Therapy and Research (the Bragg Centre), to commence operations in 2024-25.
- Option 2: Two PBT centres, equivalent to one machine per 13 million people, with the second centre to commence operations in approximately 2028:

2a. (preferred) One each in SA and NSW

- 2b. One each in SA and Queensland
- Option 3: Three PBT centres, equivalent to one machine per 9 million people, with the second centre to commence operations in approx. 2028 and third centre in approx. 2031:

¹ Medical Services Advisory Committee (MSAC) Application 1638

3a. One each in SA, NSW and Victoria

- 3b. One each in SA, NSW and Queensland
- 3c. One each in SA, Victoria, Queensland

The Strategy also provides the following recommendations to ensure the safe, equitable, and cost-effective implementation of PBT into cancer care.

- a. A national clinical governance committee to oversee coordinated referral and treatment planning to enable equitable access and efficient resource use.
- b. Nationally agreed data collection, including patient utilisation, demographic indicators including Aboriginal and Torres Strait Islander and CALD status, clinical quality indicators, including PREMS and PROMS², and cancer outcomes.
- c. Workforce planning, education, and training to build capacity and capability for both technical skills (including engineering and maintenance) and multidisciplinary clinical expertise.
- d. An agile approach to the use of PBT, given that the indications for treatment have potential to change rapidly as new national and international clinical evidence for PBT is gathered.
- e. A transition to future investment in compact PBT units, noting that technological advances are delivering smaller units which can be retrofitted into existing radiation therapy bunkers.
- f. A networked approach to PBT delivery to ensure equitable patient access to multidisciplinary wrap-around care, clinical trials and research facilities within service delivery.

² Patient-reported experience measures (PREMs) and Patient-reported outcome measures (PROMs)

1. Background

- In March 2023, the Minister for Health and Aged Care the Hon. Mark Butler asked Cancer Australia to lead the development of a PBT Strategy for cancer patients in Australia.
- PBT is an emerging form of external beam radiation therapy that uses heavier particles (protons) instead of X-rays (which are used in conventional photon radiation therapy, PRT). PBT is used to treat cancers that have not spread and are located near vital organs, which makes it preferred for brain cancers especially in children. PBT may cause fewer side effects than conventional radiation therapy as it delivers more targeted radiation to the cancerous tissue, causing less damage to nearby healthy tissue.
- In November 2020, Medical Services Advisory Board (MSAC) Application 1638 Proton beam therapy for paediatric and rare cancers recommended public funding for PBT for specific rare cancers in paediatric, adolescent, young adult and adult populations (Application 1638) particularly cancers of the brain, central nervous system, head and neck.
- The MSAC economic evaluation was a cost-utility analysis comparing PBT and PRT based upon the proposed cost of PBT (excluding capital costs) of around \$43,000 per course versus around \$14,000 for PRT. MSAC considered that the estimates of cost-effectiveness were uncertain due to limitations in the evidence.
- In evaluating cost effectiveness of PBT, MSAC accepted that, by sufficiently
 decreasing the rates of toxicity events across eligible patients, PBT would result in
 sufficient net improvements in quality of life and cost offsets from reduced provision of
 healthcare resources to be acceptably cost-effective overall in the MSAC-supported
 rare cancer types.

2. Methodology

1. Consultation

Cancer Australia convened an expert PBT Strategic Planning Group (PBT- SPG) that included Australian and South Australia (SA), New South Wales (NSW), Queensland, Victorian, and Western Australia (WA) State Government representatives, clinicians, researchers and consumers to support the development of an equitable, evidence-based, cost-effective approach to the provision of PBT to Australian cancer patients.

The SPG considered the following questions:

- 1) Which cancer patients are likely to benefit from PBT now, and into the future?
- 2) What is the optimal number of PBT machines/centres and at which location(s) in Australia should these be positioned to ensure equitable cost-effective access?
- 3) How will PBT be integrated into networked cancer care, including involvement of multidisciplinary teams to ensure best practice comprehensive care for cancer patients?
- 4) How will patients be supported to access PBT, including options for travel and accommodation?
- 5) What are the minimum data requirements to inform implementation and evaluation of PBT delivery in Australia?

Cancer Australia also consulted with the Australian Capital Territory, the Northern Territory and Tasmania Health departments, with particular emphasis on questions 3) and 4).

2. Evidence Review

Cancer Australia commissioned the Sax Institute to conduct a rapid review of high-level evidence for the current and emerging use of PBT for cancer treatment including the indications defined in the Medical Services Advisory Board (MSAC) Application 1638 – Proton beam therapy for paediatric and rare cancers. Summary findings of the Evidence Review are at <u>Appendix C</u>, and <u>the report is available in full on Cancer Australia's website</u>.

Overall, there is a need for more high-quality evidence to better understand effectiveness, safety, and cost-effectiveness of PBT for various cancer types and patient populations. There is no recent research on effectiveness of PBT for Aboriginal and Torres Strait Islander people, people of Culturally and Linguistically Diverse (CALD) backgrounds, or other priority populations.

3. International benchmarking

According to the <u>Particle Therapy Co-Operative (PTCOG</u>), 21 countries currently have at least one operating PBT machine, and at least one PBT centre as of May 2023. The USA has the highest number of machines (44), followed by Japan (19) and the UK (6; including 2 in publicly-funded centres).

Table 1 shows the number of PBT machines in each country per one million people. When the Australian Bragg Centre for Proton Therapy and Research (the Bragg Centre) is completed in

2024-25, Australia will have approximately the 16th highest ratio (0.0383 machines per one million people/1 centre per ~26 million people), in line with South Korea at 0.0390. Two centres in Australia (1 per ~13 million) would benchmark Australia 12th highest, in line with Taiwan, Belgium and the United Kingdom. Three centres (1 per ~9 million) would benchmark Australia 6th highest, closer to Austria and Switzerland. There is potential for Australia to provide PBT for cancer patients from New Zealand, Southeast Asia and the South Pacific.

Country	PBT machines per million people	Number of machines
Netherlands	0.1751	1
Denmark	0.1726	1
Japan	0.1344	19
USA	0.1178	44
Switzerland	0.1155	1
Australia with three national centres	0.1180*	3
Austria	0.111	1
Sweden	0.099	1
Czech Republic	0.0934	1
UK	0.0884	6
Belgium	0.0863	1
Taiwan	0.084	3
Australia with two national centres	0.0786*	2
Germany	0.0597	5
Italy	0.0496	3
France	0.046	4
South Korea	0.039	2
Australia with one national centre	0.0393*	1
Russia	0.0343	5
Poland	0.0264	1
Spain	0.0214	2
Thailand	0.0143	1
China	0.0021	4
India	0.0007	1

Table 1: PBT machines per million people internationally

* Assumption: centre/s per Australian population of 25.42 million people²

4. Modelling

Cancer Australia conducted modelling of interjurisdictional patient flows to PBT facilities and costs of travel. Consideration was given to travel and accommodation for patients and accompanying family members for an average length of treatment time of 30 days.

In the absence of robust national data, modelling in this report is based on expert clinical, epidemiological, policy and cost effectiveness advice. As such, it is qualitative and

predictive based on expertise at a point in time. Modelling can be found at Appendices D and E.

3. Considerations for implementation of PBT

The Australian Cancer Plan (the Plan) sets a national reform agenda for the next 10 years, covering the continuum of cancer care including prevention, early detection, diagnosis, treatment, supportive care, survivorship, palliative care, and end-of-life care, to improve experiences and cancer outcomes for all Australians. The implementation of PBT has been situated in this context with key considerations related to equity, service delivery and infrastructure highlighted below.

1. Equity factors

- Australia needs to be well positioned to respond to emerging patient demand so that PBT services are implemented nationally in an equitable way, with a prioritisation for patients with MSAC-recommended indications.
- Expansion to non-recommended indications risks further inequity for Australians needing PBT if centre capacity is re-directed towards privately-funded patients in preference to patients receiving MBS- indicated treatment.
- Equitable access to PBT requires wrap around services for patients and their families, including culturally appropriate support. Information for patients, care givers and health professionals about the benefits of PBT, its limitations and availability, will also be important to enable access and equity.
- The burden of interstate travel may reduce the willingness of patients to opt for PBT. Reducing out-of-pocket costs for travel and accommodation and bulk-billing delivery of PBT services will be important for promoting access and affordability. All states and territories have a financial assistance scheme to support patient travel for service delivery, but only ACT, NT and Tasmania cover travel out of state.
- Achieving equity in person-centred optimal cancer care, including for Aboriginal and Torres Strait Islander people, people living in rural and remote areas and those from CALD backgrounds, requires evidence-based policy and service planning to provide additional support for those with poorer cancer outcomes and experiences.
- Provision of culturally responsive care and information that addresses communication barriers, poorer health literacy, and cultural variations, and telehealth for rural and remote patients for PBT planning may enable more equitable access.

2. Service delivery factors

- Service delivery planning must account for patients who require higher levels of support, such as paediatric, adolescent and young adult patients and their carers, given the specific factors that impact their cancer experience, including developmental stage of life at diagnosis and educational disruption.
- Whilst the current MSAC-recommended indications are unlikely to expand in the short term, workforce and service delivery planning must consider potential increases in patient demand for additional non-MBS indications.
- The rapid review of the evidence commissioned by Cancer Australia identified emerging evidence for benefit of PBT in oesophageal cancer, head and neck cancer, left-sided breast cancer, prostate and lung cancer (see <u>Appendix C</u>). Case estimates by the Bragg Centre for 2025 (based on international evidence) include head and neck cancer (1,250 cases) oesophageal cancer (120 cases) and left sided

breast cancer (600 cases). Cancer Australia has modelled patient demand (based on estimates) over the period 2025-2040 (see <u>Appendix D</u>).

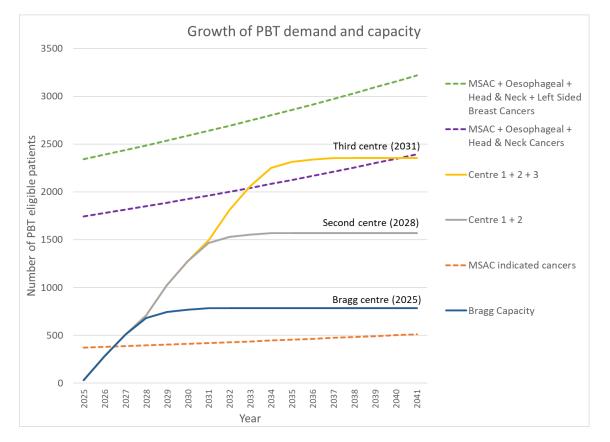
3. Infrastructure factors

- Technological advances may make PBT more cost-effective in the future, as newer units are small enough to be installed in existing radiation therapy bunkers. While these miniaturised units are associated with lower capital expenditure and maintenance costs, costs are still significantly higher than traditional linear accelerators which deliver photon beam radiation therapy.
- Similarly technological advances are likely to accelerate PBT centre construction. The Bragg Centre will take approximately seven years from planning in 2018 to operation in 2025. Newer centres are likely to require a shorter timeline for implementation if miniaturised PBT machines become widely commercially available, and existing radiation therapy bunkers are available for installation.
- Miniaturised machines are expected by some radiation oncology experts to become available in Australia within the next two to three years, although realistic time to implementation may be closer to five years.
- Carbon ion radiation therapy is also in development. Currently, evidence of superior clinical outcomes compared to PBT is limited. In addition, this technology is significantly more expensive to build (estimated \$300 million for a single centre). NSW is currently considering the viability of a carbon ion radiation therapy centre within the Westmead Health precinct.

4. Detailed recommendations and rationale

Cancer Australia has estimated the growth in patient demand including and beyond current MSAC indications to include cancers where international evidence is showing benefit from PBT, noting that not all patients eligible for PBT will take up treatment due to the burden of interstate travel (Figure 1). Detailed methodology and limitations of this modelling are at Appendix D.

Figure 1: Estimated PBT demand, including growth in demand for PBT for oesophageal, head and neck, and left sided breast cancers; and capacity of proposed PBT centres



1. Number and location of centres and timing of roll-out

Three options are provided for potential national roll-out of PBT for Australia.

A comparison of the percentage of patients who would need to travel, the average travel cost and the total annual national cost for each option is at <u>Table 2</u> below.

Table 2: Considerations for PBT Centre Locations: patient travel burden and associated costs

Number of machines (per million)	Options	Timing	PBT Centre Location	% patients who must travel interstate to receive treatment (Aboriginal and Torres Strait Islander patients ³)	Average travel cost per patient (travelling from out of state)	Annual national travel costs
One (One per 26 million)	Option 1	Bragg Centre expected 2024-25	SA (current⁴)	93% (95%)	\$13,406	\$4,577,946
Тwo	Option 2a		SA/NSW (preferred)	61% (61%)	\$13,513	\$3,055,678
(One per 13 million)	Option 2b	2028	SA/ Queensland	73% (66%)	\$13,423	\$3,587,689
Thinory	Option 2c		SA/Victoria	67% (87%)	\$13,868	\$3,411,786
-	Option 3a		SA/NSW/Victoria	36% (53%)	\$14,011	\$1,872,769
Three (One per 9	Option 3b	2031	SA/NSW/ Queensland	41% (32%)	\$13,833	\$2,074,857
million)	Option 3c		SA/Victoria/ Queensland	47% (59%)	\$13,694	\$2,355,646

Option 1: The Bragg Centre to commence in 2024-25.

 The Bragg Centre is well advanced and has indicated it will meet the 2025 demand for Medical Services Advisory Committee (MSAC) recommended indications (372 patients per annum (65.8% children and adolescent and young adults, and 34.2% adults) as estimated in the <u>MSAC Application 1638</u>)⁵, with capacity for growth in additional non-MBS indications (378 patients) up to a total of 750 patients per annum.

Option 2: Two national centres with the second centre to commence in approximately 2028.

- Two PBT centres would benchmark Australia internationally at the mid-range of centres (one PBT machine per 13 million people (see <u>Table 1</u> under Methodology). A second centre could meet the demand for a further 750 patients per annum for indications beyond current MSAC recommendations, for example oesophageal cancers and head and neck cancers for which preliminary international evidence has demonstrated clinical benefit of PBT. Modelling suggests that there may be a further 1,742 potential patients in Australia in 2025 with these indications.
- Option 2a (preferred). A second centre would improve equitable access by reducing the need for patients to travel interstate, with only 61% of patients travelling to a centre in NSW, less than Victoria (67%) and Queensland (73%). A second centre in NSW would also optimise access for Aboriginal and Torres Strait Islander people from across Australia, noting that approximately one third (34%) of Aboriginal and Torres Strait Islander people live in NSW, and 39% of Indigenous Australians live in SA and NSW combined.
- <u>Option 2b</u>. A second centre in Queensland would facilitate access for 29% of Aboriginal and Torres Strait Islander people who live in Queensland. However, it would require more

³ Percentage of Aboriginal and Torres Strait Islander patients nationally who must travel for treatment.

⁴ Australian Bragg Centre for Proton Therapy and Research (the Bragg Centre) is already under construction in South Australia.

⁵ MSAC Application 1638 recommended public funding for PBT for specific rare cancers in paediatric, adolescent, young adult and adult populations particularly cancers of the brain, central nervous system (CNS), head and neck.

patients to travel interstate (73%) than NSW and Victoria, with associated higher national travel costs. While Queensland does not yet have a Comprehensive Cancer Centre (CCC), the Queensland government has proposed to incorporate PBT into the CCC establishment build, scheduled to be completed in 2028.

Option 3: Three national centres, with the second to commence in approximately in 2028 and a third centre to commence operations in approximately 2031.

- Three PBT centres would benchmark Australia internationally at the high range of centres (one machine per 9 million people (see <u>Table 1</u> under Methodology). Evidence of increases in demand along with demonstrable patient benefit and cost effectiveness will be required to justify and inform a possible third centre and its location.
- The advantage of three national centres is that local service availability would be increased, and equity of access optimised, as the proportion of patients needing to travel would be reduced. A third centre could meet the demand for a further 750 patients per annum over and above a second centre, potentially for additional cancer types. For example, for left sided breast cancers, for which limited international studies have shown potential benefit of PBT, with modelling suggesting a further 2,342 patients in 2025 (see Figure 1 above). However, there is a greater risk of over-capitalising leaving the first two PBT machines idle, especially if they have not yet reached capacity when the third centre opens.
- If a third centre is funded, the **preferred option** is a second centre in NSW and a third centre in Victoria (<u>Option 3a</u>) based on lower percentage of patients required to travel and associated lower national travel costs.
- A second centre in NSW and a third centre in Queensland (<u>Option 3b</u>) would optimise access for Aboriginal and Torres Strait Islander people for the 68% who live in SA. Queensland and NSW combined. However, a third centre in Queensland would incur higher national travel costs and would require more complex patient referral pathways, with patients from either NSW or Victoria be split evenly across the other states due to centre capacity (see <u>Table E 3</u>).
- <u>Option 3c, with centres in SA, Queensland and Victoria,</u> requires more patients to travel and would incur higher national travel costs. It would also require more Aboriginal and Torres Strait Islander patients to travel than options 3a and 3b.

Western Australia, ACT, Northern Territory and Tasmania have not been considered as potential sites in this modelling, due to the small size of potential patient cohort in those States and territories, and the resulting travel burden placed on patients in other States. Modelling which estimates the growth in patient demand including and beyond current MSAC indications is at Appendix D. Detailed modelling of patient flows and associated interstate travel costs is at Appendix E. Results from a rapid evidence review for clinical benefit of PBT are at Appendix C.

The indicative timing of a second centre in 2028 and a possible third centre in 2031 has been determined on the basis of the lead time required to build a PBT centre (up to 5 years), including the potential for miniaturised PBT machines with shorted installation times, allowing time for the Bragg Centre to reach full capacity (2031), the potential for emergence of evidence for new indications, and the forecast of growth in population (15%) and cancer incidence (22%) from 2021-2031.

The period between commencement of a second centre (2028) and a third centre (2031) will require evidence of increases in demand along with demonstrable patient benefit and

cost effectiveness to inform the third centre and its location, once a second centre is operational.

2. National Clinical Governance committee

- As PBT is a new, high-cost and evolving treatment option, a national clinical governance committee is proposed to oversee equitable roll-out in Australia.
- The committee objectives would be to ensure optimal and efficient resource use and support implementation of agreed national standards for:
 - patient eligibility and referral pathways connecting local treating teams to PBT centre teams for streamlined patient navigation and continuity of care;
 - comparative PBT clinical treatment planning including transferability of treatment plans between centres to reduce duplication; and
 - collection and reporting of comparative data, including patient-reported outcomes, for evaluation of quality and effectiveness.
- In the absence of national oversight, there is a risk of sub-optimal use of PBT centres, inequity due to prioritisation of private fee-paying patients over public patients with MBS-eligible diagnoses, and failure to prospectively collect the data required to appraise outcomes and support any expansion of MSAC indications.
- Currently under Medical Treatment Overseas Program, patients are required to have comparative treatment plans approved prior to travel for PBT. MSAC has also supported a mandatory comparison of a photon therapy treatment plan with a PBT plan prior to patients being able to access PBT.

3. Data collection

- Nationally agreed and standardised data elements are required to ensure data are consistent for ongoing evidence-gathering, and linkable and interoperable with existing national datasets across the cancer care continuum.
- Key standardised elements to capture include: patient demographics, including Aboriginal and Torres Strait Islander status and CALD status; cancer outcomes, including cancer type and stage; and clinical quality indicators such as patient reported experiences and outcomes (PREMS and PROMS), and adverse events.
- Given the small number of patients who are likely to be treated initially with PBT and the need to gather evidence of PBT's utility for additional indications, non-comparable data will hamper progress in research and quality improvement.

4. Workforce planning

- It is recommended that workforce planning be a requirement for establishing new PBT centres. The future pipeline of clinical expertise should be factored into longitudinal workforce planning, including known workforce challenges such as shortage of radiation therapists¹, and potential for PBT centres to attract staff to the detriment of existing services.
- Currently, training for the Australian PBT workforce is taking place overseas. Once PBT is available in Australia, a local model for training and accreditation needs to be in place for both the technical and ancillary workforce.
- There is the potential for the Bragg Centre to provide training and accreditation for the future workforce in Australia (medical specialists, radiation therapists, medical physicists, nursing staff and allied health) using a "train-the-trainer" model, similar to the United Kingdom.

- Provision of ancillary services for PBT (particularly for paediatric patients, including clinical staff, play therapists and schooling) needs to be considered alongside treatment-specific education and training
- Inclusion of Aboriginal Liaison Officers within PBT centres will be an important consideration to support Aboriginal and Torres Strait Islander patients and families when travelling for treatment, and to co-ordinate care with local treating teams.

5. Agility in response to research

- An agile approach to the use of PBT in Australia is recommended due to the emerging evidence for new indications. Whilst at this stage the evidence for expansion of indications for PBT is limited, international experience and emerging evidence may include subsets of the following cancer types: oesophageal cancer, head and neck cancer, left-sided breast cancer, prostate cancer and lung cancer.
- There are also other clinical scenarios that may be considered in the future including repeat radiation therapy, which carries increased risk of toxicity, palliative treatment, and treatment for specific rare cancers where tumour location lends itself to better outcomes if treated with PBT.

6. Agility in response to technological advances

- Any future investment should reflect advances in technology, including the miniaturisation of PBT machines, which can be fitted into existing radiation therapy bunkers eliminating high capital infrastructure expenditure.
- Newer miniaturised PBT machines are likely to require a shorter timeline for implementation, with some radiation oncology experts estimating these to become available in Australia within the next two to three years, although realistic time to implementation may be closer to five years.

7. A networked approach to PBT delivery

- The PBT-SPG highlighted that PBT should be delivered in a CCC as part of a networked system, to support seamless transition and continuity of care between the patient's local treating team and the team delivering PBT.
- CCCs are a core element of networked care and provide integrated multidisciplinary cancer care, research, clinical trials, and education, across the cancer care continuum.
- Embedding PBT centres within a national network would ensure connectivity and sharing of expertise between CCCs, other cancer services, regional hospitals, community and primary care and would enable harmonised data capture between centres and linkage to national datasets.
- There is opportunity to leverage the work Cancer Australia has commenced as the Plan implementation priorities, in particular, the Australian Comprehensive Cancer Network (ACCN) to embed PBT into optimal cancer care and the National Cancer Data Framework and Minimum Dataset to ensure nationally linked data across the cancer continuum.

5. Appendices Appendix A – Proton Beam Therapy Strategic Planning Group membership

Table A 1: Proton Beam Therapy Strategic Planning Group Membership

Professor Dorothy Keefe PSM MD (Chair)	CEO, Cancer Australia
Professor Adam Elshaug	Cancer Australia Advisor, Health Economics and Health Policy
Mr Colin Hornby	Radiotherapy Advisor, Victoria Government Department of Health Representative, Victorian Government Department of Health
Ms Colleen Jen	Deputy Director-General, Clinical Planning and Service Strategy, Queensland Health Representative, Queensland Health
Ms Deborah Henderson	Consumer Representative, Cancer Australia Advisory Council
Dr Jeremy Croker	Radiation Oncologist, Sir Charles Gairdner Hospital Representative, WA Health
Mr Karl Briscoe	Member, Cancer Australia Leadership Group on Aboriginal and Torres Strait Islander Cancer Control, CEO, National Association of Aboriginal and Torres Strait Islander Health Workers and Practitioners (NAATSIHWP)
Ms Lindsey Gough	CEO, Women's and Children's Health Network, SA Health Representative, SA Health
Ms Lisa Schofield PSM	First Assistant Secretary, Cancer, Hearing and Chronic Conditions Division, Department of Health and Aged Care
Associate Professor Liz Marles	Member, Cancer Australia Advisory Council General Practitioner Clinical Director, Australian Commission on Safety and Quality in Health Care
Associate Professor Michael Penniment AM	Radiation Oncologist, SA Medical Director, Australian Bragg Centre for Proton Therapy and Research
Dr Maureen Harris	Project Coordinator, Medicines and Technology Unit, Government of Western Australia Department of Health, Representative, WA Health
Dr Robyn Cheuk	Radiation Oncologist, Royal Brisbane and Women's Hospital, Metro North Hospital and Health Service Representative, Queensland Health
Professor Sandro Porceddu	Radiation Oncologist, Peter MacCallum Cancer Centre Representative, Victorian Government Department of Health
Ms Skye Jacobi	Acting Deputy Chief Executive, Strategy and Governance, Department for Health and Wellbeing Representative, SA Health
Professor Tracey O'Brien	Chief Executive, Cancer Institute NSW and Chief Cancer Officer, NSW Health Representative, NSW Health
Associate Professor Verity Ahern	Radiation Oncologist, Westmead Hospital Representative, NSW Health
Professor Sanchia Aranda AM (Facilitator)	Chair, University of Melbourne School of Health Sciences

Appendix B – Medical Services Advisory Committee (MSAC) recommended indications for PBT in Australia

MSAC Application 1638 – Proton Beam Therapy for paediatric and rare cancers (November 2020)

- MSAC recommended that PBT be restricted to patients with specific malignancies as follows:
 - For an adult patient with:
 - a tumour of the base of the skull, including meningioma, chordoma or chondrosarcoma; or
 - a tumour of the vertebral column or bony pelvis; or
 - an adenoid cystic carcinoma of the salivary or lacrimal gland.
 - For a patient under the age of 25 years:
 - with a solid tumour located in:
 - the central nervous system; or
 - the orbit, including retinoblastoma; or
 - the axial skeleton or in close proximity to the axial skeleton, including bone or soft tissue sarcoma; or
 - with one of the following tumour types:
 - craniopharyngioma
 - intracranial germ cell tumour
 - neuroblastoma
 - nephroblastoma

Appendix C – Sax Institute Evidence Review, 2023, Summary

- Cancer Australia commissioned the Sax Institute to conduct a rapid review of highlevel evidence for the current and emerging use of PBT for patient populations, including those as defined by the MSAC Application 1638 – Proton beam therapy for paediatric and rare cancers.
- The report is available in full on the Cancer Australia website.
- This review included peer reviewed and grey literature published between 2020 (after the publication of MSAC Application 1638) and the date the search was completed on 4 April 2023.
- To identify publications for inclusion, the Sax Institute searched MEDLINE, the Cochrane Collaboration Library, and Web of Science. They reviewed the title and abstract of 1,212 peer-reviewed papers.
- The Sax Institute identified 24 papers to be included in the review: 4 meta-analyses, 16 systematic reviews, 3 narrative reviews, and 1 randomised control trial. In addition, they identified 2 publicly available international health technology assessments (HTAs) in the grey literature.
- The Sax Institute's search strategy focused on recent meta-analyses and systematic reviews, potentially excluding relevant primary studies, non-systematic reviews, or older publications, and limited to English language. The prioritisation of high-quality evidence may have excluded informative studies with lower levels of evidence.

Review findings

- Overall, the quality of evidence reviewed was generally low, with most studies being retrospective case series, small patient cohorts, varied techniques, and a lack of direct comparison between photon and proton therapy.
- Whilst the evidence was limited, some studies suggest that PBT has promising outcomes and improved toxicity profiles compared to photon-based radiation, particularly in paediatric cancers, central nervous system, and head and neck cancers.
- The quality of evidence was limited and of generally low quality for prostate cancer, and there was one RCT identified regarding PBT in patients with leptomeningeal metastasis from non-small cell lung cancer (NSCLC) and breast cancer.
- Two international HTAs found that PBT may result in similar overall survival and progression-free survival, but fewer toxicity events, in various adult cancers, while evidence for paediatric cancers was insufficient or of low quality.
- There was no recent research on effectiveness among different age groups, in Aboriginal and Torres Strait Islander people and CALD backgrounds.
- There is a need for more high-quality evidence to better understand the effectiveness, safety, and cost-effectiveness of PBT in various cancer types and populations.

Table C 1: Tumor-specific results from evidence review

Cancer Type	Evidence
	One systematic review suggested that PBT may offer comparable or improved outcomes compared to conventional radiation therapy for paediatric patients, depending on tumor type and location.
	Three systematic reviews reported that PBT may reduce acute and long-term toxicities in paediatric patients compared to conventional radiation therapy, helping to minimise treatment-related side effects and improve quality of life.
Paediatric cancers	Three systematic reviews noted that PBT's ability to spare healthy tissues from radiation may reduce the risk of late complications, such as secondary malignancies and growth disturbances, which can be especially significant in paediatric patients, potentially contributing to improved quality of life.
	Two systematic reviews observed that PBT treatment had been observed to cause less cognitive deficits compared with photon therapy for specific tumour types.
	One systematic review investigating the treatment of chordoma using PBT and photon therapy reported uncertainty regarding the effect of PBT compared to photon therapy on overall survival and progression-free survival due to low certainty of evidence.
CNS tumours	One systematic review reported that proton CSI may provide safer palliation of symptoms and prolong survival in patients with leptomeningeal disease.
	One systematic review reported uncertainty regarding the effect of PBT compared to photon therapy on treatment-related toxicity.
	One systematic review with 26 retrospective studies showed improved 2-year overall survival rates (33%-80%) in recurrent sinonasal, nasopharyngeal, and salivary gland tumors compared to intensity-modulated radiation therapy (IMRT; 12-68%%).
Head and neck cancer	Only one study in one systematic review reported higher 5-year progression-free survival rates (34.9%) than IMRT (20.4%) in oesophageal cancer patients.
	Two reviews reported that PBT has potentially favourable toxicological profiles compared to photon irradiation. One of these reviews found that PBT can reduce acute toxicities and late xerostomia in head and neck squamous cell carcinomas patients compared to IMRT, with lower rates of higher-grade oral mucositis for nasopharyngeal cancer patients.
	One systematic review suggested that PBT may offer higher overall survival rates compared to conventional and hypofractionated photon radiotherapy for prostate cancer patients.
Prostate Cancer	One systematic review found that PBT and carbon ion radiotherapy were both associated with a lower incidence of grade 2 or greater acute and late genitourinary and gastrointestinal toxicity compared to photon radiotherapy.
(emerging evidence)	One systematic review of particle therapy toxicity outcomes reported reduced gastrointestinal morbidities in prostate cancer patients treated with PBT compared to photon radiotherapy.
	One systematic review reported improved quality of life outcomes in prostate cancer patients treated with PBT compared to photon radiotherapy.
Lung and breast cance (emerging evidence)	This review found that one randomised controlled trial that compared proton craniospinal irradiation with photon involved-field radiotherapy in patients with leptomeningeal metastasis from non-small cell lung cancer (NSCLC) and breast cancer. The study found that proton craniospinal irradiation significantly improved CNS progression-free survival and overall survival without increasing high-grade adverse events in patients with Non-Small Cell Lung Cancer (NSCLC) and breast cancer leptomeningeal metastasis, providing high-quality evidence supporting PBT use in these cases.

Analysis of international HTAs

- Ontario Health HTA found that PBT may result in similar overall survival and progression-free survival, but fewer toxicity events, in various adult cancers, while evidence for paediatric cancers was insufficient or of low quality. The Ontario Health HTA acknowledged that high-quality evidence remains scarce, but there is ongoing research, and the rapidly evolving technology of PBT may not be fully reflected in reviews of the research.
- The Belgian Care Knowledge Centre (KCE) HTA concluded that high-quality evidence on the effectiveness of proton treatment was lacking, making it impossible to determine if it was better or worse than photon-based radiotherapy for specific adult cancers.

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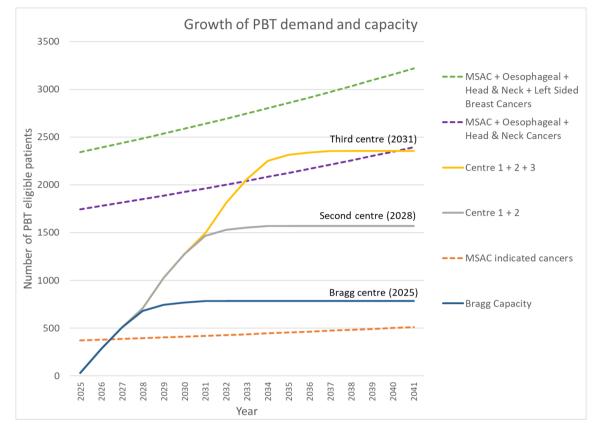
Appendix D – PBT demand and capacity modelling

Cancer Australia has estimated the growth in patient demand including and beyond current MSAC indications to include cancers where international evidence is showing benefit from PBT. It is noted that the projected clinical need is a key variable in estimating demand, yet contains a moderate level of uncertainty, noting that not all patients eligible for PBT will take up treatment due to the burden of interstate travel.

<u>Methodology</u>

- <u>MSAC 1638</u> indicated patients (372) were modelled to increase over time with population growth to 2041.
- Overall increase in cancer rates in Australia is estimated to increase by approximately 22% between 2021 and 2031³. Patient numbers for all cancers were calculated at a 22% increase in 10-year intervals, and patient values per year were interpolated based on an exponential trendline auto-calculated using Excel software.
- The Bragg Centre was modelled to include an annual total of 750 patients by 2031. These data were replicated for the capacity of the second and third centres.
- The demand modelling reflects 100% uptake of PBT treatment by all patients with MSAC and additional indications.
- Cancers with emerging evidence for PBT benefit include oesophageal, head and neck, and left-sided breast cancer patients. Based on the Dutch model-based selection indications, case numbers are as follows: oesophageal cancer (120), head and neck cancer (1,250 cases) and left sided breast cancer (600 cases), ⁴⁻⁶
- Capacity data is presented at 31 December of each year.
- The values provided are an estimate only and are intended for comparative purposes.⁴⁻⁷

Figure D 1: Estimated PBT demand, including growth in demand for PBT for oesophageal, head and neck, and left sided breast cancers; and capacity of proposed PBT centres.



Assumptions

- A 22% increase in cancer incidence every 10 years³.
- These data estimate that oesophageal cancer, head and neck cancer and leftsided breast cancer patients may be considered eligible for PBT treatment.

Table D 1: Estimated numbers of PBT eligible patients in 2025 for current MSAC indications and potential future indications.⁴⁻⁷

State	MSAC- Indicated Patients	Oesophageal cancer	Head and Neck cancer	Left-sided breast cancer	MSAC + Oesophageal + Head & Neck Cancers	MSAC + Oesophageal + Head & Neck + Left- sided Breast Cancers
NSW	118	38	397	191	553	744
Victoria	95	31	320	153	446	599
Queensland	75	24	254	122	353	475
WA	39	13	131	63	182	245
SA	26	8	88	42	122	164
Tasmania	8	3	27	13	38	51
ACT	7	2	22	11	31	42
NT	3	1	11	5	16	21
Australia	372	120	1250	600	1742	2342

National Population Modelling

<u>Methodology</u>

Australian population data were obtained from the Australian Bureau of Statistics (ABS) for 2021⁸. Projections for overall population growth in Australia is expected to increase by approximately 15% between 2021 and 2031.

The value for 2031 was calculated as 15% higher than 2021 and intermediate values interpolated via a linear trendline.

Year	Population (million)	Year	Population (million)
2021	25.69*	2027	27.33
2022	26.13*	2028	28.09
2023	26.18	2029	28.47
2024	26.56	2030	28.85
2025	26.95	2031	29.23
2026	27.33		

Table D 2: Estimated Australian population growth over 2021 to 2031

* Values obtained from the Australian Bureau of Statistics⁸

Aboriginal and Torres Strait Islander Population Modelling

Table D 3: Aboriginal and Torres Strait Islander population and non-Indigenous population nationally, and by state.^{9, 10}

Indigenous status	NSW	Victoria	Queensland	SA	WA	Tasmania	NT	ACT	Total
Aboriginal and Torres Strait Islander	278,043	65,646	237,303	42,562	88,693	30,186	61,115	8,949	812,728
Non- Indigenous	7,404,499	6,148,188	4,635,042	1,669,314	2,431,204	501,521	152,705	429,520	23,375,949
Not stated	389,616	289,665	283,793	69,646	140,128	25,851	18,775	16,033	1,234,112
TOTAL	8,072,163	6,503,491	5,156,138	1,781,516	2,660,026	557,571	232,605	454,499	25,422,788

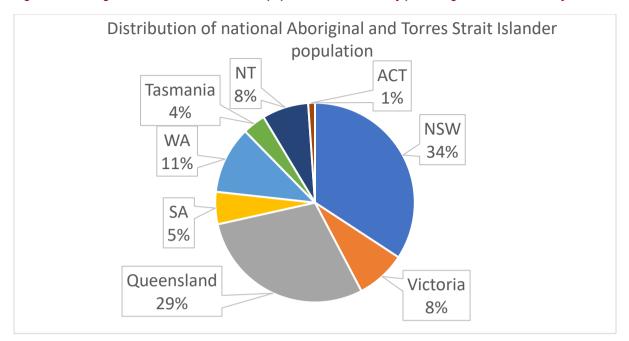


Figure D 2: Aboriginal and Torres Strait Islander population distribution by percentage across Australia by state^{9,10}

Figure D 3: Percentage of Aboriginal and Torres Strait Islander people within each State. 9, 10

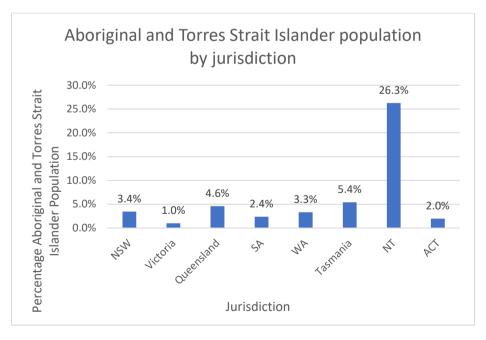


Table D 4: Distribution of Aboriginal and Torres Strait Islander people living in urban or remote areas by state.^{9,10}

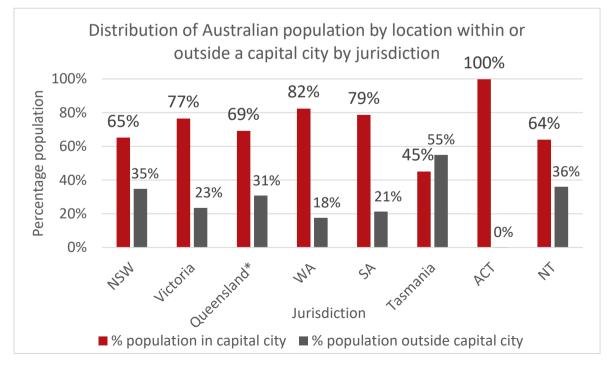
State	% of Indigenous population living in urban areas	% of Indigenous population living in remote areas	
NSW	33%	67%	
Victoria	50%	50%	
Queensland	32%	68%	
SA	56%	44%	
WA	47%	53%	
Tasmania	37%	63%	
NT	24%	76%	
ACT	99.5%	0.5%	

Rural and Remote Population Modelling

Methodology

Values for population by capital city and state were obtained from the ABS for 2021¹¹ and converted into percentages. The 'capital city' of Queensland includes South East Queensland cities, Brisbane, Gold Coast and Sunshine Coast (population values for 2021 were obtained via Queensland Government Statistician's Office.¹² Population values have not been sub-analysed by SES quintiles.





* Queensland capital city includes South East Queensland cities Brisbane, Gold Coast and Sunshine Coast

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Appendix E – Patient flows and travel costs

Cancer Australia has estimated the patient travel flow and travel costs across jurisdictions to access PBT. Patient numbers are based on MSAC-recommended indications and include two parents travelling with a child or young adult patient, and one carer travelling with an adult patient, for 30 days duration of PBT treatment.

Methodology

- The <u>MSAC 1638</u> application estimated that 372 patients nationally would be eligible for PBT in 2025. This number was used as the total number of patients within the patient flow and cost modelling.
- Patient numbers by jurisdiction were calculated using relative percentages of national population by jurisdiction, and proportion of children/AYA were calculated using the MSAC 1638 recommendation (children/AYA 65.8%, adults 34.2%) (Table E 2).
- Flight and accommodation costs were estimated as per the values listed in Tables <u>E 1</u> and <u>E 2</u>, and average cost per patient (travelling interstate), and total cost per jurisdiction and nationally were calculated. Accommodation was calculated for 30 days, and flights were costed as a return trip per person.
- Intra-jurisdictional travel costs have not been costed within this modelling.
- This cost modelling should be considered as an estimate produced for comparative purposes only.

Assumptions

The following assumptions underpin this modelling:

- 1. Cancer distribution across Australia broadly reflects population distribution and does not vary substantially by jurisdiction.
- 2. For a child or adolescent and young adult (AYA) patient travelling to a centre, three people are required to travel (one child and two parents), and two people require accommodation (two parents).
- 3. For an adult patient, two people require flights (one patient and one carer), and two people require accommodation (one patient and one carer).
- 4. All patients including children and AYA require a return flight.
- 5. Patients (grouped by jurisdiction) were allocated to PBT centres, with the objective of distributing demand equally between centres, and minimising travel distances for patients.

	PBT Centre Location	% patients who must travel interstate to receive treatment	Average travel cost per patient (travelling from out of state)	Annual national travel costs
One Centre	SA	93%	\$13,406	\$4,577,946
	SA/NSW	61%	\$13,513	\$3,055,678
Two Centres	SA/Victoria	67%	\$13,868	\$3,411,786
Two Centres	SA/ Queensland	73%	\$13,423	\$3,587,689
	SA/NSW/ Victoria	36%	\$14,011	\$1,872,769
Three Centres	SA/NSW/ Queensland	41%	\$13,833	\$2,074,857
	SA/Victoria/ Queensland	47%	\$13,694	\$2,355,646

Table E 1: Percentage of patients travelling interstate and travel costs per patient and nationally

Table E 2: Number of patients with MSAC-recommended PBT indications by state, including breakdown by children/AYA and adult patients for 2025

State	Population	% of Australian population	Number of PBT eligible patients	Number of child/AYA patients	Number of adult patients
NSW	8,072,163	32%	118	78	40
Victoria	6,503,491	26%	95	63	33
Queensland	5,156,138	20%	75	50	26
WA	2,660,026	10%	39	26	13
SA	1,781,516	7%	26	17	9
Tasmania	557,571	2%	8	5	3
ACT	454,499	2%	7	4	2
NT	232,605	1%	3	2	1
Australia*	25,422,788	100%	372	245	127

* Includes Other Territories comprising Jervis Bay Territory, Christmas Island, the Cocos (Keeling) Islands and Norfolk Island. Population values were obtained from September 2022 <u>Australian Bureau of Statistics</u> data.

Table E 3: Expected patient travel flow for patients by state (enabling even distribution across centres).

			PBT Centre Location (patient destination)						
		SA	SA/NSW	SA/ Victoria	SA/ Queensland	SA/NSW/ Victoria	SA/Victoria/ Queensland	SA/NSW/ Queensland	
	NSW	SA	NSW	SA	Queensland	NSW	50% SA 50% Queensland	NSW	
	Victoria	SA	SA	Victoria	SA	Victoria	Victoria	50% SA 50% Queensland	
Patient	Queensland	SA	NSW	Victoria	Queensland	SA	Queensland	Queensland	
home state	WA	SA	SA	SA	SA	SA	SA	SA	
	SA	SA	SA	SA	SA	SA	SA	SA	
	Tasmania	SA	SA	Victoria	SA	Victoria	Victoria	SA	
	ACT	SA	SA	Victoria	SA	Victoria	Victoria	SA	
	NT	SA	SA	SA	SA	SA	SA	Queensland	
Patient	SA %	100%	48 %	50%	48 %	39 %	34%	34%	
distribution	NSW %	-	52%	-	-	32%	-	32%	
by PBT	Victoria %	-	-	50%	-	30%	30%	-	
centre location	Queensland %	-	-	-	52%	-	36%	34%	

Table E 4: Total travel costs per state by PBT centre location.

		PBT Centre Location (patient destination)						
		SA	SA/NSW	SA/Victoria	SA/ Queensland	SA/NSW/ Victoria	SA/Victoria/ Queensland	SA/NSW/ Queensland
	NSW	\$1,510,589	N/A	\$1,510,589	\$1,585,498	N/A	\$1,548,044	N/A
Û	Victoria	\$1,204,387	\$1,204,387	N/A	\$1,204,387	N/A	N/A	\$1,266,181
state	Queensland	\$1,065,166	\$1,053,487	\$1,093,595	N/A	\$1,065,166	N/A	N/A
ıt home	WA	\$549,514	\$549,514	\$549,514	\$549,514	\$549,514	\$549,514	\$549,514
	SA	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Patient	Tasmania	\$115,184	\$115,184	\$117,174	\$115,184	\$117,174	\$117,174	\$115,184
P	ACT	\$85,053	\$85,053	\$92,862	\$85,053	\$92,862	\$92,862	\$92,862
	NT	\$48,052	\$48,052	\$48,052	\$48,052	\$48,052	\$48,052	\$51,115

Table E 5: Estimated costs of return flights per person.

	Sydney	Melbourne	Brisbane	Perth	Adelaide	Hobart	Canberra	Darwin
Sydney		\$400	\$400	\$1000	\$500	\$700	\$400	\$950
Melbourne	\$400		\$600	\$1000	\$450	\$550	\$400	\$1000
Brisbane	\$400	\$600		\$1000	\$1000	\$1000	\$500	\$1000
Perth	\$1000	\$1000	\$1000		\$1000	\$1000	\$1200	\$1000
Adelaide	\$500	\$450	\$1000	\$1000		\$1000	\$500	\$1000
Hobart	\$700	\$550	\$1000	\$1000	\$1000		\$700	\$1000
Canberra	\$400	\$400	\$500	\$1200	\$500	\$700		\$1200
Darwin	\$950	\$1000	\$1000	\$1000	\$1000	\$1000	\$1000	

Table E 6: Estimated costs of accommodation per person per night.

	Cost per person per night
Sydney	\$215
Melbourne	\$215
Brisbane	\$206
Perth	\$216
Adelaide	\$191
Hobart	\$154
Canberra	\$215
Darwin	\$176