



Australian Government

Department of Health, Disability and Ageing

**MEDICAL TREATMENT OVERSEAS PROGRAM
APPLICATION FORM FOR PROTON BEAM THERAPY (PBT)**

This application form can only be used for PBT (with or without other concurrent therapies). Applications for other treatments should use the General Application Form.

Applications should be made according to the requirements set out in *Medical Treatment Overseas Program: Guidelines for Applicants and their Australian Treating Specialists*.

Required information for the Australian Treating Specialist (ATS) to include

Applications for PBT **must** be submitted with comparative proton versus photon plans unless the applicant falls into one of the following patient cohorts:

- cranio-spinal irradiation in patients aged up to (and including) 25 years
- brain tumours in patients aged up to (and including) 5 years
- base of skull chordomas and chondrosarcomas, following maximal safe resection, in patients aged up to (and including) 25 years
- patients with a diagnosed predisposition syndrome (such as Li Fraumeni syndrome) with increased risk of secondary radiation induced malignancy and aged up to (and including) 25 years

The purpose of a comparative plan is to determine patient specific benefits for PBT over photon radiation. Moreover, the comparative plan is a clinical decision-making tool.

If comparative planning is not available from the applicant’s treating centre, a comparative planning service is available from the Australian Bragg Centre for Proton Therapy and Research (ABCPTR). Further information on the process to request a comparative plan from ABCPTR is available at <https://www.protontherapy.sahmri.org.au/referring-clinicians/>.

All applications **must** be signed and supported by the applicant’s Australian Treating Specialist/s as follows:

Patient cohort	Signed by
Aged up to and including 25	Radiation oncologist and paediatric/medical oncologist
Aged 26 and over with concurrent chemotherapy	Radiation oncologist and medical oncologist
Aged 26 and over with no concurrent chemotherapy	Radiation oncologist

The ATS should note applications are subjected to peer review by the relevant specialist college/s and Department of Health, Disability and Ageing medical officer panel. The ATS responses to the four MTOP criteria, the comparison plan (where required) and supporting

information will be used by these peer review panels to provide advice to the MTOP decision maker on whether the MTOP criteria have been met. When completing the application an ATS should ensure that there is sufficient clinical information to inform a detailed understanding of the patient situation, much like the requirements for any other multidisciplinary peer review or case conferencing.

Applications must include all relevant clinical documentation to evidence the facts stated in the application.

The information provided should conform to medicolegal and professional standards and is expected to be equivalent to what the ATS would provide if presenting their patient to a meeting of peers.

At a minimum, this should include:

- **Overseas referral:** referral letter/email to the overseas specialist or treatment centre
- **Overseas acceptance:** acceptance letter/email from the overseas treating specialist or treatment centre
- **Treatment plan:** detailed treatment plan from overseas facility which includes the total dose and number of fractions as well as any other concurrent treatment or supports
- **Medical history:** information on how and when the patient presented and treatment to date (this may be incorporated into the referral letter to the overseas facility)
- **Operative reports:** operative reports of relevant procedures
- **Pathology reports:** pathology reports of tumour type and relevant ancillary pathology (eg CSF results). Molecular profiling can still be pending at time application is submitted.
- **Imaging reports:** it is not necessary to include **all** imaging reports, just those that are required to demonstrate the diagnosis and (where relevant) post-surgery status and recurrence
- **Images:** PDF copies of 3-4 representative images from each provided imaging report (in full colour where relevant)
- **MDT outcomes:** minutes or summary from any multidisciplinary team meeting or chart round relating to the recommended treatment pathway
- **Comparative plan:** a proton versus photon comparative treatment plan in full colour (for applications for PBT where the applicant does not fall into one of the cohorts for which a comparative plan is not required)
- **Evidence:** references to supporting literature should be contained in the responses to the medical eligibility criteria (criteria A to D) but full copies of journal articles are not required

Applications submitted without evidence or missing clinically relevant documentation cannot proceed through the peer review process until this information is obtained.

Additional information for ATS consideration

In preparing an MTOP application, the ATS should consider:

- **Anaesthesia:** requirement for anaesthesia for PBT
- **Concurrent chemotherapy:** requirement for any concurrent chemotherapy (include clinical information outlining requirements)

- **Concurrent other:** requirement for any supportive care such as NG feeds or allied health therapies (include clinical information outlining requirements)
- **Medications:** any that may require a transiting permit
- **Medical devices:** supplemental oxygen/needles/syringes/feeding pumps/CPAP etc that may be required during transit
- **Fitness to fly:** the patient and the ATS are responsible for ensuring fitness to fly, including liaising directly with the airline to ensure their requirements are met

Fitness to fly, transiting permits and medical equipment requirements do not have to be arranged prior to submitting an application, nor is this information considered as part of the MTOP assessment process. However, the ATS is asked to consider these issues at the time of application to ensure that if an application is supported appropriate travel arrangements can be made.

Please submit the completed application form and supporting documentation by email to MTOP@health.gov.au.

Part 1: Applicant's details

Applicant

Family name:

Given name:

Medicare number:

Address:

Phone number/s:

Email:

If patient is under 18 years of age:

Parent 1 full name:

Parent 2 full name:

Carer

Name of carer to accompany applicant overseas:

Relationship to applicant:

Address:

Phone number/s:

Other sources of funds

Have any other funds been received (or are likely to be received) to assist with the cost of the applicant's medical treatment and/or associated expenses? This may include funds from compensation schemes, private health insurance, public donations or charitable organisations.

Yes/No (please circle)

If yes, source of funding:

Nominated representative

Would the applicant like to nominate another person to receive information relating to the applicant's application or participation in the MTOP? (For example, spouse, social worker, other family members)

Yes/No (please circle)

If yes:

Name:

Relationship to applicant:

Part 2: Privacy Notice

The Australian Department of Health, Disability and Ageing is collecting personal information about you for the purpose of determining your eligibility for financial assistance under the Medical Treatment Overseas Program (MTOP) and for administering the MTOP, including the amount of financial support provided to you if your application is successful. This involves collecting personal information about you from Services Australia for the purpose of determining your eligibility for Medicare benefits and, if necessary, collecting personal information about you from your referring Australian treating specialist and your proposed overseas treating specialist.

The Department of Health, Disability and Ageing can be contacted by telephone on (02) 6289 1555 or free call 1800 020 103 or by using the online enquiries form at [Department of Health, Disability and Ageing's website](#).

If you do not provide all the personal information required, the Department may not be able to determine your eligibility for financial assistance or provide you with financial support if your application is successful.

The Department may disclose your personal information to:

- your Nominated Representative (if applicable)
- Services Australia (for example, to confirm Medicare eligibility)
- your referring Australian treating specialist
- your proposed overseas treating specialist/s and administration staff of the facility.

Additionally, if your case is the subject of a media report or inquiry, the Department or the Minister may respond, including publicly, to correct or to confirm the content of the report or inquiry. Such a response may involve disclosure of personal information about you.

The Department may also disclose de-identified information relating to your medical condition to medical expert groups. You may be identifiable, however, if your medical condition is rare.

The Department has an [APP privacy policy](#) which you can read on the [Department of Health, Disability and Ageing's website](#). You can also obtain a copy of the APP privacy policy by contacting the Department using the contact details set out above. The APP privacy policy contains information about:

- how you may access the personal information the Department holds about you and how you can seek correction of it; and
- how you may complain about a breach of the Australian Privacy Principles.

The Department may disclose some of your personal information to overseas recipients (such as the proposed treatment facility where you will receive medical treatment).

CONSENT TO COLLECTION OF SENSITIVE INFORMATION AND APPLICANT DECLARATION

1. I consent to the Department of Health, Disability and Ageing collecting confidential health information about me for the purpose indicated above.
2. I hereby state that all information provided in this application is true and correct to the best of my knowledge. I have read and understood the *Financial Assistance to Australian Residents Requiring Medical Treatment Overseas Guidelines for Applicants (Guidelines)*

Applicant's/Parent's/Guardian's signature

Date

Full name of person signing (in block letters)

Nominated carer's signature (if different to above)

Date

Full name of person signing (in block letters)

Parts 3 and 4 must be completed by the Australian treating specialist.

Part 3: Diagnosis/treatment

<p>Applicant's treating radiation oncologist in Australia</p>	<p>Name: Address: Preferred phone number: Alternate phone number: Email: <input type="checkbox"/> Please tick if you do NOT want your email/phone details shared with MTOP applicant</p>
<p>Applicant's treating medical oncologist in Australia</p>	<p>Name: Address: Preferred phone number: Alternate phone number: Email: <input type="checkbox"/> Please tick if you do NOT want your email/phone details shared with MTOP applicant</p>
<p>Applicant's diagnosis</p>	<p>Diagnosis:</p>
<p>Treatments to be delivered overseas concurrently with PBT (must be included in quote from overseas treating facility)</p>	<p>Please tick: <input type="checkbox"/> Anaesthetic for PBT <input type="checkbox"/> Concurrent treatment (eg chemotherapy), please briefly specify: <input type="checkbox"/> NG feeds, please briefly specify: <input type="checkbox"/> Allied health, please briefly specify: <input type="checkbox"/> Other, please briefly specify:</p>

Proposed overseas treating specialist and facility	Name of overseas specialist: Phone number: Email: Treatment centre/facility: <i>Please attach:</i> <ul style="list-style-type: none"> • <i>letter/email from ATS to proposed overseas specialist/facility referring the applicant</i>
Acceptance by overseas facility	Has the applicant been accepted as a patient of the proposed overseas facility and met all requirements to have PBT delivered in this facility? Yes/No (please circle) <i>Please attach:</i> <ul style="list-style-type: none"> • <i>a letter/email of acceptance from the overseas facility</i> • <i>detailed treatment plan from the overseas facility that includes:</i> <ul style="list-style-type: none"> • <i>proposed total dose and number of fractions</i> • <i>consultations including planning, monitoring and follow up</i> • <i>any concurrent treatment or therapies, such as chemotherapy or allied health</i> • <i>any additional supports required to enable treatment, such as anaesthetic or nutritional support</i> • <i>an itemised quote from the overseas facility that includes all the above proposed treatment</i>
Treatment timeframe	Length of proposed PBT treatment (excluding planning and post recovery treatment):
Travel requirements	Are there any specific travel requirements for the applicant on either the flight to the overseas treating facility or return flight to Australia? Yes / No (flight to overseas treating facility) Yes / No (return flights to Australia) If yes, please briefly outline the specific travel requirements (for example, special medical equipment, oxygen supply):

Medical attendant	<p>Is there are requirement for a medical attendant or support worker to accompany the patient overseas?</p> <p>Yes/No (please circle)</p> <p>If yes, is there a requirement for the medical attendant or support worker to stay with the patient for the duration of the patient's while overseas receiving treatment overseas?</p> <p>Yes/No (please circle)</p> <p><i>If yes to either of the above, please attach a letter/email to this application which indicates:</i></p> <ul style="list-style-type: none"><i>• why an attendant is required to support the applicant</i><i>• the type of support required</i><i>• the duration the support is required</i><i>• the details of clinical qualifications and/or skills the attendant must have in order to support the applicant</i>
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Part 4: Medical Eligibility Criteria

An explanation of the medical eligibility criteria is set out in the Guidelines. Referring Australian treating specialists should refer to the Guidelines when completing this section of the application form to ensure that all relevant information is provided in support of their patient.

Criterion A: The proposed overseas treatment or an effective alternative treatment must not be available in Australia in time to benefit the applicant.

It must be demonstrated that the proposed treatment will provide a significant improvement in the health outcome compared to any treatment available in Australia including photon radiation therapy.

A1: Are there any alternative surgical or medical options (not involving radiation therapy) available for this patient at this time?

Yes/No (please circle)

If yes, please explain why these are not considered to be an effective alternative to radiation therapy at this time.

A2: How was the decision made that radiation therapy is indicated and that PBT is the optimal treatment modality, or that proton vs photon comparative planning should be undertaken to determine the optimal treatment modality?

- Multidisciplinary team meeting

Please insert:

- name of meeting:.....
- date of meeting:.....

Please attach:

- *evidence of outcomes of multidisciplinary team meeting*

Or

- Chart round

Please insert:

- Name/location of chart round:.....
- date of chart round:.....

Please attach:

- *evidence of outcomes of chart round*

A3: Is the applicant in one of the cohorts for which a comparative plan is not required?

Yes/No (please circle)

If yes, please tick, **and then move on to Criterion B:**

- Cranio-spinal irradiation in patients aged up to (and including) 25 years
- Brain tumours in patients aged up to (and including) 5 years
- Base of skull chordomas and chondrosarcomas, following maximal safe resection, in patients aged up to (and including) 25 years
- Patients with a diagnosed predisposition syndrome (such as Li Fraumeni syndrome) with increased risk of secondary radiation induced malignancy and aged up to (and including) 25 years

A4: If the applicant requires a comparative plan, please provide discussion under 1-4 below (as many as relevant):

1. Reduced treatment toxicity

- *ATS (Radiation Oncologist) to state which and why*

2. Dose escalation

- *ATS (Radiation Oncologist) to outline dose and reasoning*

3. Reirradiation

- *ATS (Radiation Oncologist) to explain why PBT is required*

4. Second cancer risk

- *ATS (Radiation Oncologist) to include information on the cancer predisposition syndrome*
- *ATS (Radiation Oncologist) to include statement on the 'clinically meaningful' lifetime difference*

Please attach:

- *Proton versus photon comparative treatment plan (in full colour)*

Criterion B: The treatment must be significantly life extending and potentially curative for the condition that is being treated.

The application must contain evidence that indicates that:

- The applicant's condition is life-threatening and
- PBT treatment is significantly life-extending for any patient with the condition and
- PBT treatment is potentially curative for any patient with the condition

B1: Is radiation therapy for this condition significantly life-extending and potentially curative?

Please provide the rationale/evidence – this can be in the form of citing treatment guidelines or treatment protocols (ie an extensive literature review is not required when established pathways are being followed)

Please include a numerical prognosis, 5-year survival rate or similar

B2: Is systemic therapy required concurrently with PBT to ensure life-extension and cure?

Yes/No (please circle)

If yes, please provide:

- details of the therapy to be delivered, including timing of cycles
- the rationale/evidence for why this treatment needs to be provided concurrently overseas.

(Note: If therapy is being provided under a standard multimodal therapy protocol, please specify the treatment plan including protocol name, originating cancer treatment group and planned treatment arm – comprehensive discussion regarding the underpinning rationale for this protocol is not required)

B3: Is another modality of radiation therapy (eg photon or carbon ion) required concurrently with PBT to ensure life-extension and cure?

Yes/No (please circle)

If yes, please provide the rationale/evidence for why this treatment needs to be provided concurrently overseas

Criterion C: There must be a real prospect of success for the applicant.

Evidence must be provided to demonstrate that PBT has a strong probability of success *for the individual patient*. This includes information regarding the stage of the applicant's medical condition, the results of any prior treatment and any co-morbidities.

C1: Is the individual patient expected to have the outcomes outlined in Criteria B?

Yes/No (please circle)

If yes, please:

- briefly outline the factors present that indicate that this individual patient is likely to have the expected outcomes as outlined in your response to Criterion B (e.g. their tumour and clinical presentation is consistent with the features of the tumours and patient cohort in the literature)
- confirm that the prognosis for this patient is as per the prognosis identified in your response to Criterion B.

If no, please:

- outline mitigating factors that would indicate that this individual patient may not have the expected outcomes as outlined in your response to Criterion B (e.g. they have a high ECOG, the tumour has features that don't align with those in the literature or falls into a sub-group of the presented literature. the patient has features that don't align with the cohort in the literature for example age outside the study population)
- include a numerical prognosis, 5-year survival rate or similar for this patient, and cite any references to support this

C2: Are there any co-morbidities (other than the tumour to be treated with PBT)?

Yes/No (please circle)

If no, move on to **Criterion D**.

If yes, provide details:

C3: Are these comorbidities expected to impact on the delivery or outcomes of the treatment?

Yes/No (please circle)

If yes, provide details:

Criterion D: The treatment must be accepted by the Australian medical profession as a standard form of treatment for the applicant's condition.

Evidence must be provided that PBT is accepted by the Australian medical profession as a standard form of treatment in the patient's specific circumstances.

D1: Is Australian medical profession support for PBT as a standard form of treatment for the applicant's condition evidenced by the applicant's condition being included as a recognised indication for PBT in the RANZCR Particle Therapy Position Statement?

Yes/No (please circle)

If yes, no further information is required for Criterion D.

If no, please provide the rationale/evidence for the application in relation to criterion D.

Australian treating radiation oncologist name:

Australian treating radiation oncologist signature:

Date:

Australian treating paediatric/medical oncologist name:

Australian treating paediatric/medical oncologist signature:

Date:

APPLICATION CHECKLIST

The following information is required for the medical assessment:

- Detailed treatment plan from overseas facility which includes the total dose and number of fractions as well as any other concurrent treatment or supports
- Supporting medical documentation including:
 - referral letter/email to the overseas specialist or treatment centre
 - acceptance letter/email from the overseas treating specialist or treatment centre
 - relevant medical history (if not covered in referral letter/email to the overseas facility)
 - relevant operative reports
 - pathology reports including tumour type and ancillary pathology (molecular profiling can still be pending at time application is submitted)
 - key imaging reports (both pre- and post-surgery where relevant)
 - PDF copies of 3-4 representative images from each provided imaging report (in full colour where relevant)
 - outcomes from any multidisciplinary team meeting or chart round relating to the recommended treatment pathway
 - a proton versus photon comparative treatment plan in full colour (for applications for PBT where the applicant does not fall into one of the cohorts for which a comparative plan is not required)
 - references to supporting literature should be contained in the responses to the medical eligibility criteria (criteria A to D) (full copies of journal articles are not required)
- Page 6 - Applicant must sign the Consent, Application and Declaration form
- Part 3 - Australian treating specialist must complete this section
- Part 4 - Australian treating specialist must complete this section
- Page 16 - Australian treating radiation oncologist must sign application and Australian treating paediatric/medical oncologist must sign the application unless the patient is 26 or over and not receiving concurrent chemotherapy

Medical assessment of the application CAN NOT commence until all medical information, including the comparative plan (where required), has been submitted to MTOP.

The following documents are required for administrative purposes. Medical assessment of the application can commence without these documents:

- Copy of Medicare Card
- Copy of Birth certificate
- Copy of Passport
- Evidence of permanent residency (for non-Australian citizens)
- Itemised quote from overseas facility that includes all proposed treatment (including concurrent treatments and supports)