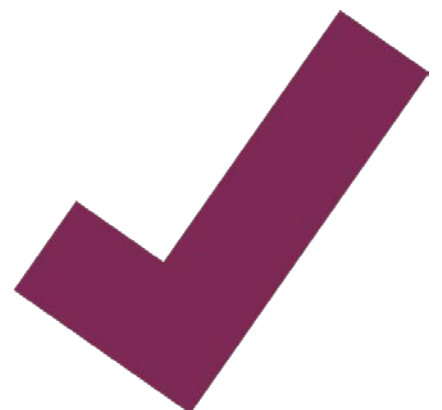


**Standard Operating
Procedure:
Process for applying for
Proton Beam Therapy and
subsequent treatment
centre allocation for
eligible patients**



Standard Operating Procedure: Process for applying for Proton Beam Therapy and subsequent treatment centre allocation for eligible patients

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Standard Operating Procedure statement

This document sets out how the process for applying for Proton Beam Therapy (PBT) and the subsequent treatment centre allocation of eligible patients will operate during the period between October 2018 and March 2022

This version reflects any changes made as a result of public engagement and consultation.

Equality and Health Inequalities statement

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document we have:

- given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it, and
- given regard to the need to reduce inequalities between patients in access to, and outcome from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities.

1 Introduction

- 1.1 This document sets out how the process for applying for Proton Beam Therapy (PBT) and the subsequent treatment centre selection of eligible patients will operate during the period between October 2018 and March 2022.
- 1.2 The intended audience is those responsible for managing the commissioned PBT capacity available to the NHS. It should be read in conjunction with the NHS England commissioning policies relating to the provision of PBT which can be found at:
<https://www.england.nhs.uk/commissioning/spec-services/npc-crg/group-b/b01/>
<https://www.england.nhs.uk/commissioning/spec-services/highly-spec-services/pbt/>
- 1.3 NHS England is the statutory body responsible for the commissioning of PBT services. The policies that can be found following the above links set out which patients are eligible for PBT and the support that NHS England will provide for patients to access services.
- 1.4 There is a single process for the operational management of applications for PBT, including the allocation of treatment centre. This process is managed by the National Proton Office. Email address: england.protonreferrals@nhs.net
- 1.5 It should be noted that the first part of the standard operating procedure (SOP) applies to all applications for PBT. The second part applies where there is a need to allocate eligible patients (i.e. those whose application has been approved) to an NHS commissioned PBT provider. All patients eligible for PBT in line with NHS England clinical commissioning policy will be offered treatment at a provider commissioned and funded by the NHS.

2 Background

- 2.1 NHS England has been referring patients eligible for PBT overseas for treatment since 2008. The routine commissioned providers of this service are University of Florida Health Proton Institute, Jacksonville, USA and Westdeutsches Protonentherapiezentrum (WPE) Essen, Germany. Both centres have been through a full NHS England procurement or quality assurance process and both are fully compliant with the NHS England Service Specification for overseas PBT providers which can be found at: <https://www.england.nhs.uk/publication/service-specifications-proton-beam-therapy-service-adults-and-children/>
- 2.2 On occasion, some adult patients may be treated at the Paul Scherrer Institut, Villigen, Switzerland. This will particularly be for those patients unable to travel to the United States for either clinical or other personal issues such as visa restrictions

- 2.3 The first NHS PBT centre at The Christie NHS Foundation Trust Manchester commenced treating patients in December 2018. The second NHS PBT centre will open in 2020 at University College London Hospitals NHS Foundation Trust (UCLH).
- 2.4 The NHS PBT centres will go through a period of clinical and capacity ramp-up during which time the clinical indications and number of patients able to be treated within these centres will increase based on capacity and safety plus ability to meet critical pathways of treatment starting times, to a point at which it will no longer be necessary to refer any NHS patients overseas for treatment. It is anticipated this will be by March 2022. For some patients with certain indications, in order not to significantly compromise cure rates, and for complex combined treatment modality pathways of care, conventional radiotherapy will be given until adequate capacity is available in the two NHS facilities as safety precludes treatment abroad.
- 2.5 It is anticipated that once both NHS PBT centres are at full capacity, the majority of referrals will be geographically based, i.e. referrals from the north of England, including from Scotland, Northern Ireland and north Wales will be to The Christie and those from the south of England to UCLH.
- 2.6 Until the NHS PBT service has sufficient capacity to treat all NHS patients, **the default referral route will be to established routine commissioned providers overseas.**
- 2.7 NHS England will only fund referrals made to PBT centres commissioned by NHS England.

3 Timescales

- 3.1 The standard period for providing a substantive response to an application for PBT (i.e. a decision on the patient's eligibility and allocated treatment centre) is a maximum of 10 working days from the date of receipt of a fully completed application to the date the applying clinician is informed of the outcome. Urgent cases will be considered and responded to within 2 working days.

4 Application Process

- 4.1 All applications for PBT must be made using the web-based Proton Referral Portal. All applying clinicians must be registered to access this portal. Details of how to register can also be found following this link <https://protons.protontherapyreferrals.nhs.uk>
- 4.2 Referrals can only be made by a Consultant Clinical Oncologist from an NHS commissioned specialised cancer centre following discussion at the relevant

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multi-disciplinary team (MDT) meeting. Applications cannot be accepted from GPs, patients or their non-clinical representatives. This is because:

- it is unlikely they would be in possession of the technical clinical detail including imaging that is necessary for consideration of the application
- the process is designed to enable an NHS clinician to apply for commissioning approval to support the referral for NHS treatment to the appropriate NHS England commissioned provider.

4.3 It is important that any social or logistical problems that might impact on patient care, safeguarding or ability of the patient or family to manage travel or treatment abroad are fully explored and must be contained within the referral.

4.4 Consent for treatment(s) or any associated clinical trials will be undertaken at the treatment centre, once the treating clinician has met and assessed the patient. However, patients will be informed of the need to transfer detailed information about their case, including test results and scans through the NHS Referral Portal in order to be assessed for funding and approval. If approved, it will be necessary to transfer information from the referring centre to the treatment centre, which may be abroad. Written consent for follow up data to be used for the purposes of clinical audit, service evaluation and improvement and health care research will also be taken by the referring clinical team. Follow-up data will be held at the treating centre. Anonymised data may be shared for the purposes outlined.

4.5 The Referral Portal is designed to ensure applications contain all necessary information for a decision to be made and applications cannot be submitted without all mandatory fields completed.

4.6 Imaging must be sent through the Image Exchange Portal (IEP) from the referring hospital.

4.7 Complete PBT applications will then be circulated via the portal to one of the PBT National Clinical Panels, virtual panels made up of leading oncologists and specialist surgeons from across the UK. Panels are currently in place for:

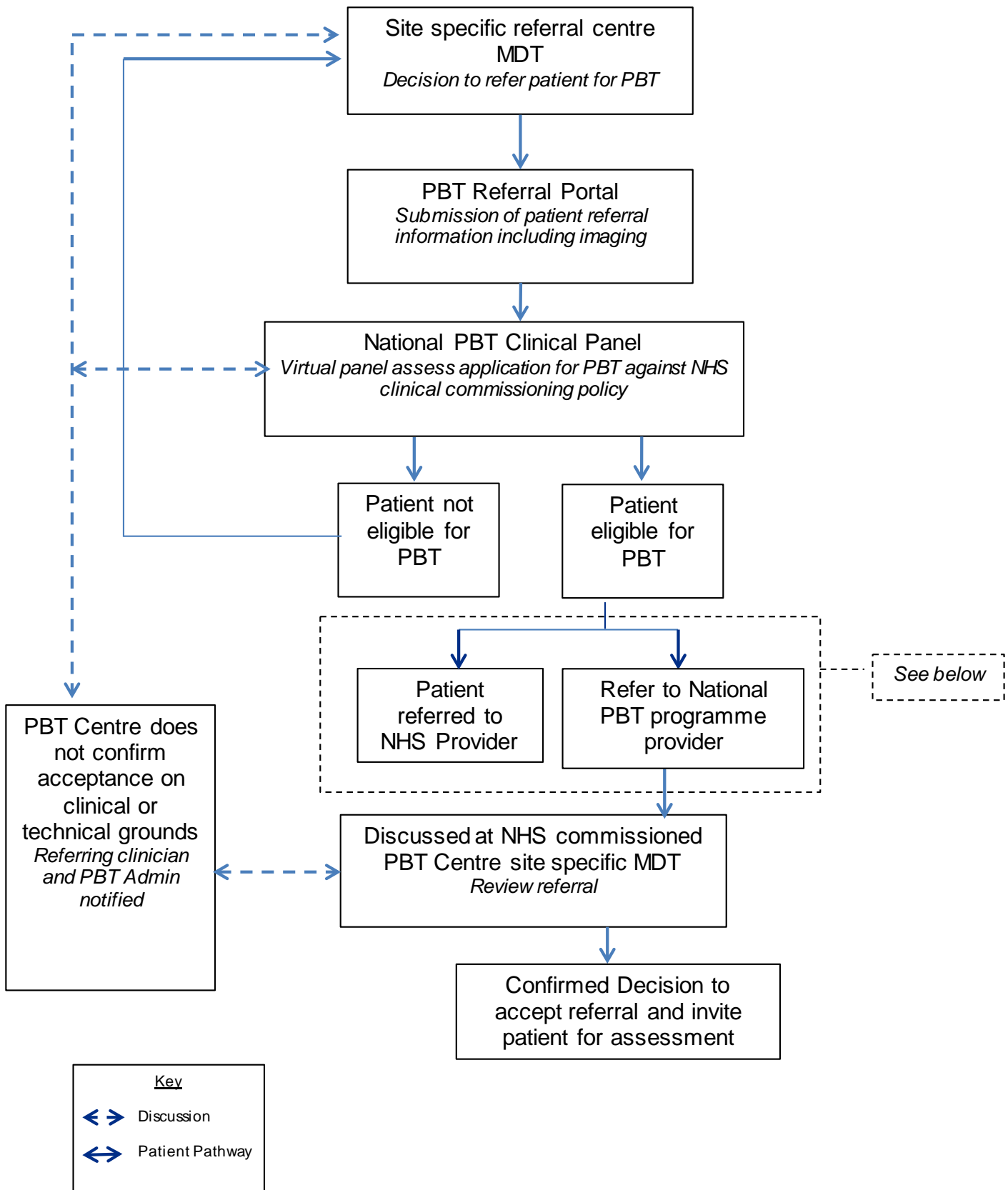
- Paediatric and Teenage & Young Adult (TYA) Cancers
- Adult Skull base and Central Nervous System (CNS)
- Spinal and Sacral Tumours (Adult and TYA)
- Head and Neck Tumours (Adult and TYA)

4.8 The panel will individually review the application and supporting documentation. Panel members can see imaging through a secure PBT version of IEP (which is also used for transferring images abroad as this complies with international governance requirements).

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- 4.9 Panel members will respond via the portal with recommendations about approval and clinical management, including whether the case meets clinical criteria. For some diagnoses there are more specific criteria. (Appendix 1). They will also provide comments about the case and especially on safety of treatment overseas or timing of treatment. If there is a NO response, further detail on the reasons why is included.
- 4.10 The PBT National Clinical Panel Chair will review the responses from the panel and make the concluding recommendation/decision as to whether or not the patient meets the NHS England commissioning criteria. A minimum of three consistent replies are needed before making a decision for paediatric and TYA and skull base patients, and two consistent replies for head and neck and spinal patients. In the event of a lack of consensus the Chair will facilitate further discussion via email to reach a consensus view. This may include clarifying any misunderstanding on clinical criteria or poor application details. In particularly difficult cases the Chair may wait for or seek more replies before a final decision is made. On occasion, further advice may be sought from proton clinical experts at one or more of NHS England's commissioned providers prior to a final decision being made.
- 4.11 The Chair will send a formal reply to referring clinicians including feedback from panel members especially in the event of a NO decision.
- 4.12 For applications that meet the NHS England commissioning criteria, the PBT National Clinical Panel chair through delegated authority from NHS England, confirms in writing to the clinician making the application that a referral can be made to one of the PBT providers commissioned by NHS England. This may include feedback from panel members. The National Proton Office sends a copy of the travel and accommodation policy plus the PBT centre referral checklist if appropriate, with a YES decision.
- 4.13 For applications that do not meet the NHS England commissioning criteria, the PBT National Clinical Panel Chair through delegated authority from NHS England confirms in writing to the clinician making the application that the patient does not meet the eligibility criteria and that a referral for PBT may not be made. This will include relevant feedback from panel members.
- 4.14 It is the responsibility of the referring clinical team to communicate the commissioning decision and rationale to the patient and family.
- 4.15 All panel and commissioning replies are kept on file within the portal.

4.16 PBT Referral Pathway



5 Decisions & Treatment Centre Selection

5.1 In confirming that an application has been successful and that a patient is eligible for PBT, the PBT National Clinical Panel chair will make a recommendation as to which NHS England commissioned PBT centre the patient should be referred.

5.2 The National Proton Office will have the following options available to them:

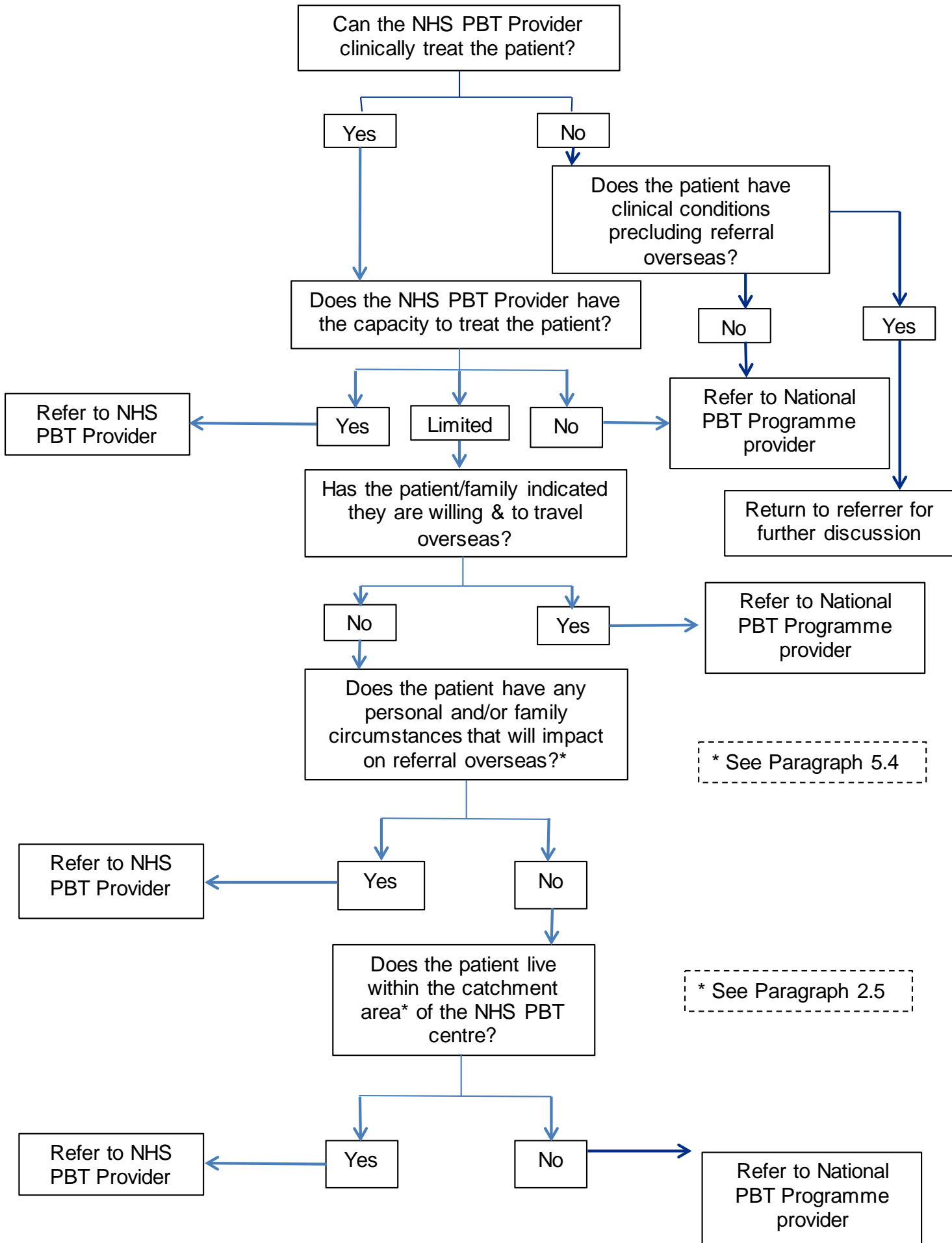
- Referral to an overseas provider:
 - WPE, Essen, Germany (paediatric and TYA only)
 - UFHPTI, Jacksonville, USA (all ages)
 - PSI, Villigen, Switzerland (adults only)
- Referral to an NHS PBT Centre
 - The Christie, Manchester (from 2018) (paediatric and TYA from 2018, all ages from 2019)
 - UCLH (from 2020) (all ages)

5.3 The National Proton Office will allocate patients to a treatment centre following the framework below which has been designed following public engagement and consultation. The patient's clinical circumstances will always take priority. Other factors may be taken into consideration after it is confirmed that the patient's clinical circumstances are not the primary factor. It is essential that the capacity and operational resilience of the PBT treatment centres (especially those in the early stages of development) is maintained to ensure provision of high quality and robust services to all NHS patients.

5.4 In order to appropriately allocate a patient to a treatment centre, it is essential that applications are fully completed and include information on any personal and/or family circumstances that may be taken into account by the National Proton Office when making a decision. These include (but not limited to):

Tier 1 (absolute)	Tier 2 (additional information that may be taken into account)
<ul style="list-style-type: none"> • Non-clinical restrictions on travel for either patient or carer (e.g. visa restrictions) 	<ul style="list-style-type: none"> • Other dependants (e.g. siblings or elderly relatives)
<ul style="list-style-type: none"> • Pregnancy (2/3rd Trimester - patient or carer) 	<ul style="list-style-type: none"> • Single parents
<ul style="list-style-type: none"> • Safeguarding concerns, including parental access issues 	<ul style="list-style-type: none"> • Education (especially TYA patients)
<ul style="list-style-type: none"> • Ongoing court and/or legal proceedings preventing travel overseas 	<ul style="list-style-type: none"> • Relative living close to a PBT centre
<ul style="list-style-type: none"> • Physical or mental ill health impacting on carer's ability to travel overseas 	<ul style="list-style-type: none"> • Work restrictions (e.g. self-employed, ability to take time off work)

5.5 PBT Treatment Centre Allocation Pathway



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- 5.6 If the patient is approved for treatment and recommended to an NHS PBT centre, the patient will be referred directly onto the centre with clinical information transferred via the referral portal.
- 5.7 If the patient is approved for treatment and recommended to an NHS England commissioned overseas provider, then the referring clinician will need to download the application from the portal and send this as the referral directly to the recommended overseas provider, along with any updated or additional material requested by them.

Appendix 1:

Low grade gliomas and glioneuronal tumours

Selected Low Grade Gliomas are included, namely those with a more circumscribed growth pattern (Pilocytic Astrocytoma, Pleomorphic Xanthoastrocytoma), as well as paediatric type Diffuse Astrocytomas and Oligodendrogliomas (which do not have IDH mutations or 1p19q codeletion but have a range of other changes e.g. BRAF V600 or KRAS mutations, alterations in MYB or FGFR1), and adult type Oligodendroglioma which is IDH-mutant and 1p19q co-deleted. Low grade Glioneuronal tumours e.g. Ganglioglioma are also included. Adult type Diffuse Astrocytoma, WHO grade II, IDH mutant and 1p19q non co-deleted is excluded. Typically, this will show ATRX loss and TP53 mutation, but these changes are not present in all cases.

Atypical Teratoid Rhabdoid Tumours (ATRT)

Only cases with completely resected or near complete resection, good performance status and stable on chemotherapy will be included.