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Welsh Health Specialised
Services Committee (WHSSC)

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Proton Beam Therapy for adults with cancer

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Policy Statement

Welsh Health Specialised Services Committee (WHSSC) will commission high energy Proton Beam Therapy (PBT) for adults with cancer (selected clinical indications) in accordance with the criteria outlined in this document.

In creating this document WHSSC has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources.

Welsh Language

WHSSC is committed to treating the English and Welsh languages on the basis of equality, and endeavour to ensure commissioned services meet the requirements of the legislative framework for Welsh Language, including the [Welsh Language Act \(1993\)](#), the [Welsh Language \(Wales\) Measure 2011](#) and the [Welsh Language Standards \(No.7\) Regulations 2018](#).

Where a service is provided in a private facility or in a hospital outside of Wales, the provisions of the Welsh language standards do not directly apply but in recognition of its importance to the patient experience, the referring health board should ensure that wherever possible patients have access to their preferred language.

In order to facilitate this WHSSC is committed to working closely with providers to ensure that in the absence of a Welsh speaker, written information will be offered and people have access to either a translator or 'Language-line' if requested. Where possible, links to local teams should be maintained during the period of care.

Decarbonisation

WHSSC is committed to taking assertive action to reducing the carbon footprint through mindful commissioning activities. Where possible and taking into account each individual patient's needs, services are provided closer to home, including via digital and virtual access, with a delivery chain for service provision and associated capital that reflects the WHSSC commitment.

Disclaimer

WHSSC assumes that healthcare professionals will use their clinical judgement, knowledge and expertise when deciding whether it is appropriate to apply this policy.

This policy may not be clinically appropriate for use in all situations and does not override the responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or their carer or guardian.

WHSSC disclaims any responsibility for damages arising out of the use or non-use of this policy.

1. Introduction

This document has been developed as a Commissioning Policy for the planning and delivery of high energy Proton Beam Therapy for adults resident in Wales. This service will only be commissioned by the Welsh Health Specialised Services Committee (WHSSC) and applies to residents of all seven Health Boards in Wales.

1.1 Plain Language Summary

For the sake of clarity, this document distinguishes between **Proton Beam Therapy (PBT)**, and all other types of radiotherapy which are grouped together as **conventional radiotherapy**.

Radiotherapy is the use of ionising radiation to treat cancer. Radiotherapy includes Proton Beam Therapy (PBT), which is provided by specialist centres. Radiotherapy also includes treatments provided by all British radiotherapy centres, such as conventional radiotherapy, Intensity Modulated Radiotherapy (IMRT), Image Guided Radiotherapy (IGRT), Stereotactic Radiotherapy (SBRT, SABR), Brachytherapy, Superficial radiotherapy, electron therapy, and Molecular Radiotherapy (i.e. therapeutic radioisotopes such as radioiodine).

PBT refers to the use of high-energy proton beams used instead of conventional radiotherapy to treat cancer and tumours. PBT utilises a different method of conformally targeting a high dose to a tumour compared to conventional radiotherapy and may thus allow dose escalation to the treatment volume when compared to conventional treatment. As a result of the characteristic properties of PBT (i.e. to stop at a precise depth in tissue with little dose beyond that point), it can allow treatment with reduced volumes of irradiated normal tissues in nearly all situations when compared to conventional radiotherapy. It is this property that allows treatment to be delivered with potentially reduced risks of late side effects, and which can permit escalation of radiation dose to radical levels for some tumours situated next to sensitive structures such as the spinal cord or brain, where conventional radiotherapy may be difficult.

Patients who meet the clinical criteria outlined in this policy are eligible for proton beam radiotherapy and should be considered for it by specialised multidisciplinary teams (MDT).

The highly selected adult indications within this policy include rare cancers situated at the skull base or around the spine that present major challenges for conventional radiotherapy as they are situated close to very sensitive normal tissues that limit the dose that can be given. There is evidence that in these situations PBT allows a higher dose to be given to the tumour safely with improved probabilities of local tumour control and potential for cure.

Craniospinal irradiation (CSI) is the term used to describe the delivery of radiation therapy to the whole brain and spinal cord and is used with curative intent in certain primary brain or spinal tumours. The tumour types are ones which predominate in the paediatric, teenage and young adult age ranges, and are very rare in older adults (aged >25 years). CSI is most often given in combination with chemotherapy and after surgery. The management pathway is complex and has time critical factors in order to maximise tumour control and cure rates. For types of cancer requiring CSI, there is supporting evidence of improved treatment outcomes, such as reduction in acute side effects including spinal deformities, infertility and cardiac toxicity, when PBT is utilised.

1.2 Aims and Objectives

This policy aims to define the commissioning position of WHSSC on the use of Proton Beam Therapy for adults with cancer.

The objectives of this policy are to:

- ensure commissioning for the use of Proton Beam Therapy is evidence based
- ensure equitable access to Proton Beam Therapy
- define criteria for people with cancer to access treatment
- improve outcomes for people with cancer

1.3 Epidemiology

Chordomas are a very rare type of cancer which is diagnosed in just one in one million people per year. That means that about 700 patients are diagnosed with chordoma each year in all of Europe. Chordoma is diagnosed most often in people in their 50s and 60s, but it can occur at any age. Skull base chordomas occur more frequently in younger patients, while spinal chordomas are more common later in life. About twice as many men are diagnosed with chordoma as women. While chordoma can run in families, this is very rare¹.

¹ [Chordoma Foundation](#)

Chondrosarcoma is one of the most common bone sarcomas of adulthood, characterised by the production of tumour cartilage². The age standardised incidence may be as high as 0.25/100,000 per year in males and 0.2/100,000 in females per year [UK age standardised rates report 0.19/100,000 population in the UK (NCIN)], with the most common age being between 30–60 years. There are approximately 100–120 new cases per year in the UK³.

Tumours arising in the nasal cavity and paranasal sinuses are uncommon with an incidence of about 5.6 cases per million. The most common type of cancer is squamous cell cancer (52%) but other rare types occur and include adenocarcinoma, adenoid cystic carcinoma and esthesioneuroblastoma (arising from the olfactory epithelium). Overall this group of tumours would have an incidence of about 360 cases per annum in the UK.

Medulloblastoma

Standard risk medulloblastoma is the most common indication for CSI, and most commonly occurs in children. There are approximately 12 patients over the age of 25 years diagnosed with medulloblastoma per year in England (Public Health England, 2017). Between 66% and 85% (Sengupta et al, 2017; Carrie et al, 1994) of these cases would be standard risk medulloblastoma, and so in summary approximately 8-10 patients per year would require CSI for standard risk medulloblastoma. Extrapolating this estimate for the population of Wales would mean approximately one patient every two years. The actual number suitable for PBT could be lower if some were unfit for travel within an appropriate timeframe.

Intracranial germinomas

A germinoma is a type of germ cell tumours which are rare tumours which overall occur at a rate of around 1 per million per annum, equivalent to around 53 new cases per annum in England, of which only 15 patients per annum would be expected to be aged >25 years (WHO, 2016; CBTRUS Statistical Report, 2017). Around 40% - 67% of patients aged >25 years will have germinomas, implying 6 - 10 patients with intracranial germinomas per annum aged >25 years in England. Adults with both localised and metastatic intracranial germinomas are currently usually treated with CSI. Germinoma (localised and metastatic) is exquisitely radiosensitive, with excellent cure rates.

² [R. F. Riedel, N. Larrier, L. Dodd, D. Kirsch, S. Martinez, and B. E. Brigman, "The clinical management of chondrosarcoma," *Current Treatment Options in Oncology*, vol. 10, no. 1-2, pp. 94-106, 2009](#) as cited in UK Guidelines for the Management of Bone Sarcoma 2010

³ [National Institute for Health and Clinical Excellence \(NICE\), "Guidance on Cancer Services— Improving Outcomes for People with Sarcoma: the Manual \[Needs assessment, Evidence\] review, List of recommendations\]," 2006,](#) (Developed by the National Collaborating Centre for Cancer). as cited in UK Guidelines for the Management of Bone Sarcoma 2010

It is therefore expected that 6-10 adult patients per year in England may require CSI, and should receive PBT as long as the delay between referral and treatment does not lead to a risk of clinically significant adverse outcomes, especially for metastatic patients. Extrapolating this estimate for the population of Wales would mean approximately one patient every two years.

Very rare selected indications for CSI

There are some extremely rare presentations of other central nervous system tumours where CSI is indicated and meets the prognostic criteria as described in 2.1 (the patient should have a clear indication for CSI which is defined as being curable (leading to normal or near-normal life expectancy); have a reasonable disease specific 5-year survival expectation; and have no comorbidities likely to limit life expectancy to less than 5 years).

1.4 Current Treatment

PBT is a current treatment option for a group of specific cancers in adults as set out in this policy.

1.5 Proposed Treatment

Proton Beam Radiotherapy (PBT) is the use of high-energy proton beams, instead of high energy linear accelerator-generated external beam radiotherapy using X-rays (photons) and electrons, to treat cancer and tumours. In certain situations, PBT may have clinical advantages over conventional radiotherapy techniques because of the distinct depth-dose characteristics of PBT deposition in human tissue, when compared to high energy X-rays and electrons. PBT is given in a number of daily treatments over several weeks.

1.6 What NHS Wales has decided

WHSSC has carefully reviewed the evidence of high energy Proton Beam Therapy for cancer. We have concluded that there is enough evidence to fund the use of Proton Beam Therapy, within the criteria set out in section 2.1.

1.7 Relationship with other documents

This document should be read in conjunction with the following documents:

- **NHS Wales**
 - All Wales Policy: [Making Decisions in Individual Patient Funding requests](#) (IPFR).
- **WHSSC policies and service specifications**
 - WHSSC Commissioning Policy: [Proton Beam Therapy for children, teenagers and young adults with \(CP148\)](#)
- **Relevant NHS England policies**
 - NHS England Highly Specialised Commissioning, [Proton Beam Therapy Service \(adults and children\) Service Specification](#)
 - Clinical Commissioning Policy: [Proton Beam Radiotherapy \(High Energy\) for Skull Base Tumour Treatment](#)
 - Clinical Commissioning Policy: [Proton Beam Radiotherapy \(High Energy\) for Paediatric Cancer Treatment](#)
 - Clinical Commissioning Policy: [Proton Beam Radiotherapy \(High Energy\) for Young Adult Cancer Treatment](#)
- **NICE Guidance**
 - [Improving outcomes in children and young people with cancer \(CSG97\)](#) 24 August 2005

2. Criteria for Commissioning

The Welsh Health Specialised Services Committee has approved funding of Proton Beam Therapy for adults with cancer, in line with the criteria identified in this policy.

Patients meeting all of the following criteria **and** subject to being approved by the UK National Proton Clinical Reference Panel will be routinely funded for high-energy proton treatment.

This arrangement will be kept under regular review.

This policy will be reviewed on an annual basis. The All Wales PBT Advisory Group (AWPROT), a subgroup of the Clinical Oncology Sub-Committee (COSC) of the Welsh Scientific Advisory Committee (WSAC), will be asked to scrutinise any new evidence to help inform WHSSC of any change to the list of indications included in this document.

2.1 Inclusion Criteria

2.1.1 General Principles

Age

Adults are defined as individuals aged 18 years old and over. There is an overlap with the TYA group whose age extends from 16-25 years of age. The age limit applies to the start of treatment. Patients who transition between age groups at any stage during the pathway should be managed according to the original referral criteria assuming this is clinically appropriate.

MDT discussion/management

The patient's management should have been fully discussed by the appropriate specialist MDT. Comprehensive diagnosis and staging should have been carried out.

Consultation with the patient and final recommendation for PBT should be made by a Consultant Clinical Oncologist. This is important in order that the general radio-therapeutic issues have been explained. This should include an explanation of the relative merits of PBT compared with high quality conventional radiotherapy.

2.1.2 General Criteria

- A clear indication for radiotherapy and defined as curable and with cancer survival expectation of 40% 5 year survival and no co-morbidities likely to limit life expectancy to <5 years, plus WHO performance status 0-1.
- There should be **no** evidence of distant metastasis.

2.1.3 Specific Diagnostic Criteria

Base of Skull tumours

Patients with skull base tumours should have had appropriate and maximal safe resection, so that minimal residual disease and adequate clearance from critical dose limiting normal structures (such as brain stem and optic structures) are achieved before referral.

Clinically useful dose escalation with PBT should be reasonably expected compared to photon radiotherapy:

- Chordoma
- Chondrosarcoma
- High naso-ethmoid, frontal and sphenoid tumours with base of skull involvement.
- Adenoid cystic carcinoma with perineural invasion
- Esthesioneuroblastoma

Spinal and Para spinal tumours

- Spinal and Paraspinal Bone and Soft Tissue Sarcoma
- Spinal Chordoma

Patients with spinal and paraspinal tumours should have had successful maximal resection and adequate clearance from critical dose limiting normal structures.

Patients should have adequate stabilisation without metal placement that will compromise target volume determination or dose distribution.

Clinically useful dose escalation should be reasonably expected compared to photon radiotherapy.

The list of commissioned indications will be kept under review by WHSSC and the All Wales PBT Advisory Group (AWPROT). New indications will be considered for inclusion as new evidence emerges based upon their clinical and cost effectiveness.

Craniospinal irradiation

There are several diagnoses and clinical indications fulfilling the criteria for this policy. This is not a single population or diagnosis and involves selected subpopulations of patients. In general, the patient should have a clear indication for CSI defined as being curable (leading to normal or near-normal life expectancy); have a reasonable disease specific 5-year survival expectation; and have no comorbidities likely to limit life expectancy to less than 5 years.

Standard risk medulloblastoma is defined as:

- Histologically confirmed medulloblastoma,
- Non-metastatic (i.e. no metastases on MRI brain and spine and clear CSF),
- Post-surgery residual disease of <1.5cm²,
- Histological subtypes: classical, desmoplastic, nodular (large cell, anaplastic are not included).

Clinical trials

It is recognised that the eligibility criteria for PBT will evolve, partly as the result of clinical research and trials. Trials may be locally developed, national or international. Within the UK, it is assumed that PBT trials will be coordinated by CTRad's (the National Cancer Research Institute's Radiotherapy Clinical and Translational Research Working Group) Proton Beam Therapy Clinical Research Steering Committee (PBT-CRSC). Patients from Wales should have access to appropriate clinical trials. If new PBT indications are supported, for example based on clinical trial data or within NHS England through their Evaluated Commissioning Projects, access and funding for Welsh patients should be considered by AWPROT and WHSSC.

2.2 Exclusion Criteria

Proton Beam Therapy for children and teenagers and young adults is covered in a separate WHSSC policy (CP148).

The age limit applies to the start of treatment. Patients who transition between the age groups at any stage during the pathway should be managed according to the original referral criteria assuming this is clinically appropriate.

Ocular tumours suitable for low energy PBT are not covered in this policy.

2.3 Continuation of Treatment

Healthcare professionals are expected to review a patient's health at regular intervals to ensure they are demonstrating an improvement to their health due to the treatment being given.

If no improvement to a patient's health has been recorded then clinical judgement on the continuation of treatment must be made by the treating healthcare professional.

2.4 Acceptance Criteria

The service outlined in this specification is for patients ordinarily resident in Wales, or otherwise the commissioning responsibility of the NHS in Wales. This excludes patients who whilst resident in Wales, are registered

with a GP practice in England, but includes patients resident in England who are registered with a GP Practice in Wales.

2.5 Patient Pathway (Annex i)

- Patients with the cancers listed above must all be considered by the appropriate specialist MDT.
- Where radiotherapy is considered and patients are eligible according to the criteria as listed above, consideration should be made by the MDT for referral for PBT and this should be offered to patients.
- The responsible Clinical Oncologist attending the MDT should make the referral to the PBT National Clinical Panel via the online referral portal. Imaging must be sent via the Image Exchange Portal.
- If approved by the PBT National Clinical Panel:
 - Where a patient is to be treated by either the Christie Hospital or University College London Hospitals, the referral is forwarded automatically via the portal. The proton beam centre will contact the patient's local oncology team to confirm receipt of referral and request any additional information that may be required.
 - Where a patient is to be treated overseas, the referring clinician should refer directly to the recommended treatment centre.
- PBT treatment will be funded directly by NHS England and recharged to WHSSC.
- On completion of treatment, follow up will be undertaken by the treatment centre.

2.6 Designated Centres

- The Christie NHS Foundation Trust
Wilmslow Road
Manchester
M20 4BX
- University College London Hospitals NHS Foundation Trust
235 Euston Road
London
NW1 2BU
- University of Florida Proton Therapy Centre
Jacksonville
USA

2.7 Exceptions

If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for

consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All Wales IPFR Panel.

If the patient wishes to be referred to a provider outside of the agreed pathway, and IPFR should be submitted.

Further information on making IPFR requests can be found at: [Welsh Health Specialised Services Committee \(WHSSC\) | Individual Patient Funding Requests](#)

2.8 Clinical Outcome and Quality Measures

The Provider must work to written quality standards and provide monitoring information to the lead commissioner.

The centre must enable the patient's, carer's and advocate's informed participation and to be able to demonstrate this. Provision should be made for patients with communication difficulties.

2.9 Responsibilities

The responsible clinician (a Consultant Clinical Oncologist) from a relevant specialist cancer multi-disciplinary team (MDT) should refer all suitable patients who meet the pre-defined criteria to the UK National Proton Clinical Reference Panel for approval.

Following the panel approval, the clinician will then apply to WHSCC for funding for the treatment.

Referrers should:

- inform the patient that this treatment is not routinely funded outside the criteria in this policy, and
- refer via the agreed pathway.

The clinician considering treatment should:

- discuss all of the non-PBT treatment options with the patient
- advise the patient of any side effects and risks of the potential treatment
- inform the patient that treatment is not routinely funded outside of the criteria in the policy, and
- confirm that there is contractual agreement with WHSSC for the treatment.

In all other circumstances the responsible clinician should submit an [Individual Patient Funding Request](#) (IPFR).

3. Evidence

WHSSC is committed to regularly reviewing and updating all of its commissioning policies based upon the best available evidence of both clinical and cost effectiveness.

This policy was developed by the All Wales PBT Advisory Group (AWPROT) taking into account published evidence and policy guidance from other parts of the UK including NHS England.

3.1 Date of Review

This document will be reviewed when information is received which indicates that the policy requires revision. If an update is carried out the policy will remain extant until the revised policy is published.

4. Equality Impact and Assessment

The Equality Impact Assessment (EQIA) process has been developed to help promote fair and equal treatment in the delivery of health services. It aims to enable Welsh Health Specialised Services Committee to identify and eliminate detrimental treatment caused by the adverse impact of health service policies upon groups and individuals for reasons of race, gender re-assignment, disability, sex, sexual orientation, age, religion and belief, marriage and civil partnership, pregnancy and maternity and language (Welsh).

This policy has been subjected to an Equality Impact Assessment.

The Assessment demonstrates the policy is robust and there is no potential for discrimination or adverse impact. All opportunities to promote equality have been taken.

5. Putting Things Right:

5.1 Raising a Concern

Whilst every effort has been made to ensure that decisions made under this policy are robust and appropriate for the patient group, it is acknowledged that there may be occasions when the patient or their representative are not happy with decisions made or the treatment provided.

The patient or their representative should be guided by the clinician, or the member of NHS staff with whom the concern is raised, to the appropriate arrangements for management of their concern.

If a patient or their representative is unhappy with the care provided during the treatment or the clinical decision to withdraw treatment provided under this policy, the patient and/or their representative should be guided to the LHB for [NHS Putting Things Right](#). For services provided outside NHS Wales the patient or their representative should be guided to the [NHS Trust Concerns Procedure](#), with a copy of the concern being sent to WHSSC.

5.2 Individual Patient Funding Request (IPFR)

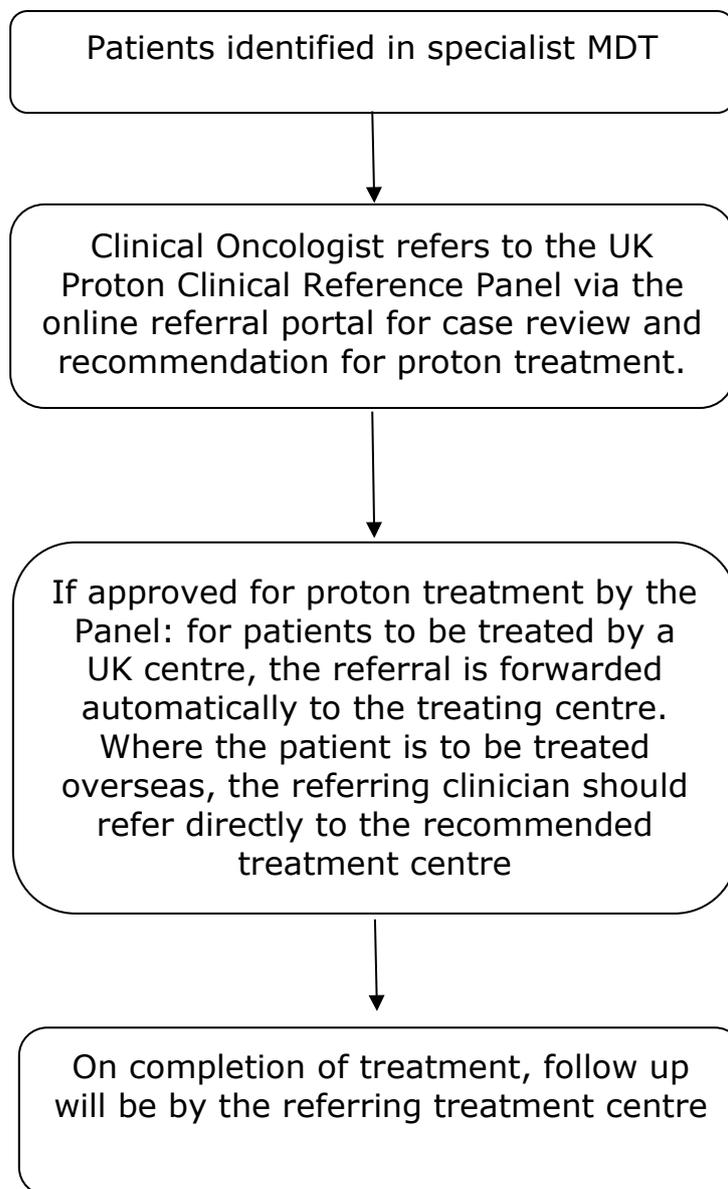
If the patient does not meet the criteria for treatment as outlined in this policy, an Individual Patient Funding Request (IPFR) can be submitted for consideration in line with the All Wales Policy: Making Decisions on Individual Patient Funding Requests. The request will then be considered by the All Wales IPFR Panel.

If an IPFR is declined by the Panel, a patient and/or their NHS clinician has the right to request information about how the decision was reached. If the patient and their NHS clinician feel the process has not been followed in accordance with this policy, arrangements can be made for an independent review of the process to be undertaken by the patient's Local Health Board. The ground for the review, which are detailed in the All Wales Policy: Making Decisions on Individual Patient Funding Requests (IPFR), must be clearly stated

If the patient wishes to be referred to a provider outside of the agreed pathway, and IPFR should be submitted.

Further information on making IPFR requests can be found at: [Welsh Health Specialised Services Committee \(WHSSC\) | Individual Patient Funding Requests](#)

Annex i Patient Pathway



Annex ii Abbreviations and Glossary

Abbreviations

AWMSG	All Wales Medicines Strategy Group
AWPROT	All Wales Proton Beam Therapy Advisory Group
IPFR	Individual Patient Funding Request
PBT	Proton Beam Therapy
SMC	Scottish Medicines Consortium
WHSSC	Welsh Health Specialised Services

Glossary

Individual Patient Funding Request (IPFR)

An IPFR is a request to Welsh Health Specialised Services Committee (WHSSC) to fund an intervention, device or treatment for patients that fall outside the range of services and treatments routinely provided across Wales.

Welsh Health Specialised Services Committee (WHSSC)

WHSSC is a joint committee of the seven local health boards in Wales. The purpose of WHSSC is to ensure that the population of Wales has fair and equitable access to the full range of Specialised Services and Tertiary Services. WHSSC ensures that specialised services are commissioned from providers that have the appropriate experience and expertise. They ensure that these providers are able to provide a robust, high quality and sustainable services, which are safe for patients and are cost effective for NHS Wales.