Title of the Committee Paper

Proton Beam Therapy

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Author: Acting Assistant Director of Planning

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Purpose of the Committee Paper

This report makes recommendations regarding NHS Wales’ commissioning position for Proton Beam Therapy (PBT) to inform the future commissioning of proton beam therapy services for Wales.

Joint Committee / Committee Resolution (insert √) to:

<table>
<thead>
<tr>
<th>APPROVE</th>
<th>ENDORSE</th>
<th>SUPPORT</th>
<th>NOTE</th>
<th>√</th>
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</thead>
</table>

Recommendation

Members are asked to:

- **NOTE** the potential equity issue regarding the provision of proton beam therapy following the publication of new Commissioning Policies in England;
- **NOTE** the Ministerial and media interest in this topic;
- **NOTE** that there is no funding included in the Integrated Commissioning Plan for PBT in 2015/16;
- **SUPPORT** the recommendation not to change the commissioning position for Wales in 2015/16; and,
- **SUPPORT** the consideration of the revision of the NHS Wales commissioning position from 2016/17 onwards in the development of the WHSSC Integrated Commissioning Plan for 2016-19.
## Governance

| Link to WHSSC Strategic Objective(s) | The publication of Commissioning Intentions for PBT is included in the Cancer and Blood Workplan in the ICP 2015/16. There is no funding included in the Plan for PBT in 2015/16. |
| Supportive evidence | Extracts from the NHS England Commissioning Policies and Strategic Outline Case are included in Annex I. |

## Engagement – Who has been involved in this work?

WHSSC attended the May meeting of the Clinical Oncology Sub-Group of the Welsh Scientific Advisory Committee to discuss this issue. An engagement workshop was also held in July with interested Welsh cancer clinicians, Health Board Cancer Lead Clinicians, the NHS England Lead Cancer Clinician and representatives of Welsh brain tumour and children’s cancer charities.

**This paper has been considered and supported by:**

<table>
<thead>
<tr>
<th>Finance</th>
<th>x</th>
<th>Clinical Evidence Evaluation Group</th>
<th>x</th>
<th>Progreme Team</th>
<th>Corporate Directors Group</th>
<th>Management Group</th>
<th>Joint Committee</th>
<th>Other</th>
</tr>
</thead>
</table>

## Commissioner Health Board affected

| Abertawe Bro Morgannwg | x | Aneurin Bevan | x | Betsi Cadwaladr | x | Cardiff and Vale | x | Cwm Taf | x | Hywel Dda | x | Powys | x |

## Provider organisation affected

| NHS Wales (please state) | x | Other NHS | x | Other private | x |

## Summarise the Impact of the Committee Paper
<table>
<thead>
<tr>
<th><strong>Equality and diversity</strong></th>
<th>The paper describes changes to the Commissioning Policies for PBT in NHS England and a future potential equity issue with access in Wales.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Legal implications</strong></td>
<td>None.</td>
</tr>
<tr>
<td><strong>Population Health</strong></td>
<td>The paper outlines the benefits of PBT compared to conventional radiotherapy in the treatment of some cancer patients.</td>
</tr>
<tr>
<td><strong>Quality, Safety &amp; Patient Experience</strong></td>
<td>None.</td>
</tr>
<tr>
<td><strong>Resources</strong></td>
<td>The resource implications for 2016/17 and future years are discussed in the paper and will be considered in the development of WHSSC’s ICP for 2016-19. There is no funding included in the Plan for PBT in 2015/16.</td>
</tr>
<tr>
<td><strong>Risks and Assurance</strong></td>
<td>There is a risk of adverse media interest and patient complaints if an equitable position with NHS England is not maintained. There is also Ministerial interest in this topic due to the development of a private facility in Newport.</td>
</tr>
<tr>
<td><strong>Health and Care Standards</strong></td>
<td>This paper relates to the Health and Care Standards</td>
</tr>
<tr>
<td><strong>Workforce</strong></td>
<td>None.</td>
</tr>
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</table>
PROTON BEAM THERAPY

1. SITUATION

For some time WHSSC has been reviewing its commissioning position for Proton Beam Therapy, including undertaking evidence appraisal and relative prioritisation of this form of radiotherapy. This report outlines a newly emergent issue of equity regarding the provision of Proton Beam Therapy (PBT).

NHS Wales has not, historically, had its own Commissioning Policy for Proton Beam Therapy. NHS England’s Commissioning Policy has been used by the UK-wide Overseas PBT Panel to make recommendations for the clinical suitability of cases to go to forward for treatment. The Panel makes treatment and funding decisions regarding PBT on behalf of England, Scotland and Northern Ireland but only makes clinical recommendations for Welsh patients. The recommendations are then considered by the All-Wales IPFR Panel for funding.

In September, NHS England agreed new Commissioning Policies for this form of specialist radiotherapy, which are now in use by the UK Overseas PBT Panel for English and Scottish patients; this leads to a potential equity issue for Welsh patients. The equity issue is particularly acute for patients from North Wales who access specialist paediatric cancer care or neurosurgery from English providers.

There is no funding in the Integrated Commissioning Plan in 2015/16 for PBT and it is therefore recommended not to change the Welsh commissioning position in year.

The Joint Committee is asked to support the consideration of the revision of the NHS Wales commissioning position from 2016/17 onwards in the development of the WHSSC Integrated Commissioning Plan for 2016-19. This will take into account the clinical preference to maintain equitable provision of this type of radiotherapy across the UK. The funding implications for 2016/17 and future years would be included in the development of the 2016-19 Plan.

There is also Ministerial and media interest in PBT due to the recent announcement of the development of a private PBT facility in Newport. For clarity, WHSSC has had no discussion with this provider. This paper makes recommendations about what indications should be funded for treatment with proton beam therapy. At this stage, it does not consider service provision.

2. BACKGROUND

2.1 Proton Beam Therapy

Proton Beam Therapy (PBT) is a form of radiotherapy which uses a high energy beam of protons to deliver a dose of radiotherapy for patients
with cancer. Standard radiotherapy uses a high dose of x-rays. The purpose of PBT is the same as conventional radiotherapy (ie to destroy or damage cancer cells) but the radiation dose control with PBT is much better than with conventional radiotherapy. PBT is usually recommended because it directs the radiation treatment very precisely to where it is needed, thereby minimising damage to surrounding tissue. Due to the better dose control, the clinical benefits of PBT compared to conventional radiotherapy are:

- to reduce the late effects of radiotherapy treatment;
- to reduce the risks of radiotherapy-induced second cancers later in life; and,
- to minimize damage to surrounding tissue.

Due to these benefits, the therapy is particularly suitable to complex childhood cancers (to reduce late effects), and tumours of the base of the skull or the spine (to minimize damage to surrounding tissue).

For patients, this means that some tumours are treated with PBT which clinicians would not otherwise treat, due to the damaging effects of conventional radiotherapy.

### 2.2 Service Provision

Currently, once treatment is agreed for a Welsh patient, patient care is co-ordinated through the UK NHS Proton Overseas Programme and patients travel to Florida for their treatment as there are no PBT facilities in the UK.

The UK government has committed £250 million to developing NHS proton beam therapy services in the UK. Two facilities are currently at an advanced stage of planning and will be located in Manchester and London. The Manchester centre (at the Christie hospital) is under construction and is due to be operational in 2018.

A private provider has also entered the market and is developing three PBT centres in the UK. One of these will be sited just outside Newport and is due to be operational in 2017.

### 2.3 Commissioning Process

WHSSC agreed a two-stage commissioning process regarding PBT looking forward up until 2020. The stages are:

1. To make recommendations regarding the commissioning intentions for PBT up until 2020. The commissioning intentions will include the clinical indications for which the service should
be commissioned, the phasing of any expansion in indications, and the predicted activity that will occur as a result.

2. To agree a formal procurement process for deciding which provider(s) will be commissioned to provide these services for the Welsh population. This will entail the development of a detailed Service Specification and a competitive tendering exercise. This may eventually entail different providers being commissioned for different geographical areas of Wales or for different sub-groups of patients.

The commissioning intentions for the service will be considered as part of the development of the Integrated Commissioning Plan for 2016-18. This paper does not make any recommendations regarding providers, which will considered during the second stage of the process.

3.0 ASSESSMENT

3.1 Welsh commissioning position - clinical indications and activity

The criteria applicable to Welsh patients in the present commissioning position include a restricted range of clinical indications. The majority (70%) of UK cases that have been historically funded are for children with cancer, with most of the remainder being for adults with skull base tumours. The historical activity for Wales is shown in the table below.

<table>
<thead>
<tr>
<th>Proton Overseas Programme Overall Figures 2008-2014</th>
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<tbody>
<tr>
<td>Country</td>
</tr>
<tr>
<td>---------</td>
</tr>
<tr>
<td>England</td>
</tr>
<tr>
<td>Wales</td>
</tr>
</tbody>
</table>

Between 2008 and 2014 the number of Welsh patients that were accepted for treatment was 15 in 6 years, an average of 2-3 per year. However 9 patients were accepted for treatment in 2014 and it is likely that referrals will continue to increase due to increasing clinical and public understanding of the therapy.

3.2 Change in NHS England Commissioning Policies

NHS England agreed a suite of three new Commissioning Policies for PBT which have been in use since September 2015. The new Commissioning Policies expand the range of indications for which PBT is commissioned in England. The main change is that the paediatric indications (which previously applied to children under the age of 16 only) are extended to
teenagers and young people up to the age of 25. There are also specific expansion in indications within all three age ranges as well. However, there is also a proposal for two more expansions of clinical indications up to 2018 (known as ‘Category 1’ and ‘Category 2’).

The detail of these expansions in indications is included in Annex I.

### 3.3 NHS Scotland Position

On behalf of NHS Scotland, the UK Overseas Panel is applying the new Commissioning Policies to applications for PBT for Scottish residents. However it is understood NHS Scotland has adopted a ‘watch and wait’ position on any further expansion in indications.

### 3.4 Activity

For Wales, there are therefore four potential phases of commissioning PBT. These are:

1. Status Quo – do not expand the indications currently commissioned for Welsh patients,
2. Commission the indications in the Revised NHS England Clinical Commissioning Policies,
3. Commission further additional clinical indications (all within Category 1),
4. Commission further additional clinical indications (Category 1 and Category 2).

The growth in activity which is forecast for Wales associated with each of the phases is shown below.

The estimated activity per year for each phase is shown below.

<table>
<thead>
<tr>
<th>Phase Description</th>
<th>No of patients</th>
<th>Phase 1 Status Quo</th>
<th>Phase 2 New Commissioning Policies 2016/17</th>
<th>Phase 3 Category 1 2017/18</th>
<th>Phase 4 Category 2 2018/19 onwards</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>9</td>
<td>15-30</td>
<td>44</td>
<td>72</td>
</tr>
</tbody>
</table>

### 3.5 Cost

The average cost per case to NHS Wales in the current arrangement is around £110k per case. NHS England and NHS Scotland are paying £75k per case in Florida. An incentive for Wales to adopt the new NHS
England policies, and to allow the UK Panel to make the treatment and funding decisions, is that Wales would then also benefit from this reduction in cost.

When the English centres are open it is estimated that the cost per case will reduce further, to approximately £40k per case. However this is predicted on the fixed costs being covered by all of the estimated demand. NHS England has suggested that if Wales do not commission the activity suggested in section 3.3 it is unlikely that NHS Wales will benefit from the full cost reduction (ie there may be differential pricing in place for Welsh patients).

However on the basis of these costs, and the activity described above, the potential costs per phase are as follows.

<table>
<thead>
<tr>
<th>Phase</th>
<th>Status Quo</th>
<th>Phase 2 New Commissioning Policies 2016/17</th>
<th>Phase 3 Category 1 2017/18</th>
<th>Phase 4 Category 2 2018/19 onwards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activity</td>
<td>9</td>
<td>15-30</td>
<td>44</td>
<td>72</td>
</tr>
<tr>
<td>Cost per case</td>
<td>£110,000</td>
<td>£75,000</td>
<td>£75,000</td>
<td>£40,000</td>
</tr>
<tr>
<td>Total</td>
<td>£990,000</td>
<td>£1.125-2.25m</td>
<td>£3.3m</td>
<td>£2.88m</td>
</tr>
</tbody>
</table>

### 3.6 Evidence Appraisal

The revised NHS England Commissioning Policies state that ‘the use of PBT was recommended by the NHS England National Radiotherapy Advisory Group in 2007. It is acknowledged that the level of the evidence is generally poor, being based largely on case series. Other more recent international PBT Programmes have included consistent conclusions on the clinical benefit of PBT in the selected cancers and clinical situations contained within the revised NHS England PBT policies e.g., American Society for Therapeutic Radiology and Oncology and Dutch, Danish and Swedish National Policies.

There is good clinical evidence for the technical ability to safely deliver PBT in specific clinical situations to achieve high local control rates and to avoid unnecessary radiotherapy dose to normal tissues, to reduce the risk of important side effects and risks of radiotherapy induced second malignancy.’

In 2013 WHSSC also undertook an appraisal of the evidence for clinical and cost effectiveness for PBT and this has been considered by the Prioritisation Panel. The conclusion was that the historical paediatric
indications are the most well-evidenced and the Prioritisation Panel recommended that these should be routinely commissioned.

However, due to the small numbers of patients being treated with PBT world-wide to date there is limited randomised clinical trial evidence available for the adult indications, and the wider Category 1 and 2 indications.

3.7 Engagement

Due to the lack of availability of high-quality evidence of clinical effectiveness, WHSSC officers discussed the issue at the June 2015 meeting of the Clinical Oncology Sub-Committee (COSC) of the Welsh Scientific Advisory Committee and members of COSC also produced a discussion paper. The clinical community’s preference is to ensure that PBT is available to Welsh patients as one of the components of high-quality integrated radiotherapy service provision. The paper also included a strong preference to maintain equity of access with England, in the context of the relatively poor outcomes for Welsh cancer patients compared to the rest of Europe.

WHSSC also held an engagement workshop in July with interested Welsh cancer clinicians, Health Board Cancer Lead Clinicians, the NHS England Lead Advisor for PBT, the Clinical Director of the PBT centre in Florida (used by the UK Overseas Programme), and representatives of Welsh brain tumour and children’s cancer charities. At this workshop it was acknowledged by all that the evidence base is growing but it will take time to build up a complete picture of clinical effectiveness, and that the effects of small numbers will always make this difficult.

The consensus of the group however was that there was clinical logic in expanding the range of indications for Wales to match the Category 1 indications outlined by NHS England. The majority of this expansion results from the extension of the current paediatric indications (for which there is good evidence) to patients in the 16-25 age range.

Most of the cancers affecting children differ from those affecting adults. They occur in different parts of the body; appear differently under the microscope and respond differently to treatment. Cure rates among children are much higher than for most adult cancers, and overall more than 80% of children are completely cured. However a significant proportion of these will experience long-term side effects from their treatment. Children are diagnosed with a wide range of cancers in the UK, of which around 25% are brain tumours. There are around 80 children per year diagnosed with cancer in Wales, and this would suggest around 20 of these will have a brain tumour.
It is well-known that paediatric brain and central nervous system tumours are physiologically different to adult tumours. These different features are apparent up until the brain matures at around 25 years of age and therefore it would be logical that the benefits of proton beam therapy in treating these tumours will also be apparent.

Following this process of engagement there is therefore support to:

- Commission the indications in the Revised NHS England Clinical Commissioning Policies for the population of NHS Wales from 2016/17 onwards;
- Commission the further additional clinical indications (all Category 1) in 2017/18;
- Review the commissioning position when the results of the Commissioning through Evaluation exercise on the Category 2 indications is known.

It was generally felt that Wales had a choice to watch and wait regarding the results of the CtE exercise before committing to supporting the adoption of the Category 2 indications. It is, however, unclear what effect only commissioning Category 1 indications will have on the cost per case when the English centres are open.

### 3.8 Risks

Whilst there is unlikely to ever be good random controlled trial evidence for the majority of the indications for PBT, there is a strong preference in the cancer clinical community for maintaining equity of access with the English commissioning position. Following the Aysha King case, which was widely covered by the media, there is also interest in this topic from patients and the media. There may be adverse media interest and complaints from patients if an equitable position is not maintained.

There are however also financial risks identified in the paper with supporting the expansion in clinical indications for PBT. The projected increase in costs could be in the region of £2m.

### 3.9 Next Steps

The next steps are to:

- Consider the revision to the NHS Wales commissioning position for PBT from 2016/17 onwards in the development of the WHSSC ICP 2016-19;
- Develop and publish a Commissioning Policy for PBT which reflects the approved position;
- Develop a Service Specification for PBT;
Engage specialist procurement advice to identify the providers after 2018;
Contract for the required service.

4. RECOMMENDATIONS

Members are asked to:

- **NOTE** the potential equity issue regarding the provision of proton beam therapy following the publication of new Commissioning Policies in England;
- **NOTE** the Ministerial and media interest in this topic;
- **NOTE** that there is no funding included in the Integrated Commissioning Plan for PBT in 2015/16;
- **SUPPORT** the recommendation not to change the commissioning position for Wales in 2015/16; and,
- **SUPPORT** the consideration of the revision of the NHS Wales commissioning position from 2016/17 onwards in the development of the WHSSC Integrated Commissioning Plan for 2016-19.
Annex I – Details of Clinical Indications

Commissioning Phase 1 – Status quo

The indications that NHS Wales currently commission are in the historical NHS England Commissioning Policy as listed in the following table.

All cases must only be considered for curative indications, have a good life expectation from other conditions and have a good performance status.

**Adult Indications**
- Base of Skull and Spinal Chordoma
- Base of Skull Chondrosarcoma
- Spinal and Paraspinal Bone and Soft Tissue Sarcomas (Non Ewing’s)

**Paediatric Indications (up to 16th birthday)**
- Base of Skull and Spinal Chordoma
- Base of Skull Chondrosarcoma
- Spinal and Paraspinal “adult type” Bone and Soft Tissue Sarcomas
- Rhabdomyosarcoma
  - Orbit
  - Parameningeal and Head and Neck
  - Pelvis
- Ependymoma
- Ewing’s Sarcoma
- Retinoblastoma
- Pelvic Sarcoma
- Optic Pathway and other selected Low Grade Glioma
- Optic Pathway and other selected Low Grade Glioma
- Craniopharyngioma
- Pineal Parenchymal Tumours (not Pineoblastoma
- Esthesioneuroblastoma
Commissioning Phase 2 – Commission the Indications in the Revised NHS England Clinical Commissioning Policies.

The indications in the new NHS England policies are listed in the table below with the new additional indications listed in italics. The policies will be adopted by the Overseas PBT Programme and will continue to be used for referral to the NHS England centres after 2018.

**Adult General Criteria**

1. 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.

2. There should be NO evidence of distant metastasis.

**Paediatric and TYA General Criteria**

3. 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, for TYA only, WHO performance status 0-1)

4. There should be NO evidence of distant metastasis with the exception of: rhabdomyosarcoma and Ewing’s Tumours where limited and only lung disease that has good partial response to the initial radiological reassessment after chemotherapy will be considered for referral and treatment.

**Adult Indications**

- **Base of skull**
  - 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**
    - Spinal and Paraspinal Bone and Soft Tissue Sarcomas
    - *Spinal chordoma*

**Paediatric Indications (up to 16th birthday)**

- Base of Skull and Spinal Chordoma
- Base of Skull Chondrosarcoma
- “Adult type” Bone and Soft Tissue Sarcomas (excluding extremities)
- Rhabdomyosarcoma (excluding extremities)

- Ependymoma
| Ewing’s Sarcoma (excluding extremities) |
| Retinoblastoma |
| Pelvic Sarcoma |
| Optic Pathway and other selected Low Grade Glioma |
| Craniopharyngioma |
| Pineal Parenchymal Tumours (not Pineoblastoma) |
| Esthesioneuroblastoma |
| Non-metastatic intracranial germ cell tumours |
| Pituitary Adenoma |
| Juvenile Angiofibroma |
| Meningioma (excluding grade 3) |
| Nasopharyngeal carcinoma |
| Salivary gland tumours |
| **Teenage and Young Adult Indications (16-up to 25th birthday)** |
| “Adult type” Bone and Soft Tissue Sarcomas (excluding extremities) |
| Rhabdomyosarcoma (excluding extremities) |
| Ependymoma |
| Ewing’s Sarcoma (excluding extremities) |
| Retinoblastoma |
| Pelvic Sarcoma |
| Optic Pathway and other selected Low Grade Glioma |
| Craniopharyngioma |
| Pineal Parenchymal Tumours (not Pineoblastoma) |
| Esthesioneuroblastoma |
| Intracranial non-germinomatous tumours |
| Pituitary Adenoma |
| Juvenile Angiofibroma |
| Meningioma (excluding grade 3) |
| Nasopharyngeal carcinoma |
| Salivary gland tumours |
Commissioning Phase 3 – Commission further additional clinical indications (Category 1)

The additional indications in the original paper which informed the NHS England Strategic Outline Case (SOC) for the new PBT centres are wider than those in the new draft Policies. These were called ‘Category 1’ indications and the additional indications are listed below.

### Adult Indications
- **Base of skull**
  - Meningioma (described as a small group)
- **Spinal and para-spinal**
  - Retroperitoneal sarcoma

### Paediatric Indications (up to 16\textsuperscript{th} birthday)
- Medulloblastoma
- Hodgkin’s lymphoma
- Neuroblastoma
- Wilm’s tumours

### Teenage and Young Adult Indications (16-up to 25\textsuperscript{th} birthday)
- Medulloblastoma
- Hodgkin’s Lymphoma (selected indications)
- Neuroblastoma (selected indications)
- Wilm’s tumours (selected indications)
- NB Pelvic sarcoma for TYA is included in the draft Policy but not in the Category 1 indications.

Commissioning Phase 4 – Commission all of the Category 1 and Category 2 Indications

The indications used to inform the NHS England Strategic Outline Case included a further much wider expansion of the adult indications. These were called ‘Category 2’ indications and are listed below.

### Adult Indications

#### Head and Neck
- Oropharyngeal cancer (subsets to be defined eg HPV related/age/stage)
- Nasopharyngeal cancer
- Re-treatment in rT1/2 N0 cancers

#### Breast cancer
- L sided inner quadrant
- Internal mammary node N3 disease involvement and requirement for RT

#### Lung cancer (stage 3)
#### Recurrent ano-rectal cancer
#### OG cancer
<table>
<thead>
<tr>
<th>Mediastinal rare cancers eg thymoma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gynaecological cancers</td>
</tr>
<tr>
<td>- Ca cervix nodal disease</td>
</tr>
<tr>
<td>- Advanced vaginal disease</td>
</tr>
<tr>
<td>Hodgkin’s/ non-hodgkin’s (esp mediastinal RT in women &lt;50)</td>
</tr>
</tbody>
</table>