SCHEDULE 2 - THE SERVICES

A. Service Specifications

| 1. | Service name | Radiotherapy services (adults and children) Service sub-heading - Brachytherapy (all ages) | |
|----|------------------------------------|--|--|
| 2. | Service specification number | 2321 | |
| 3. | Date published | September 2024 | |
| 4. | Accountable Commissioner | NHS England – Cancer National Programme of Care (NPOC) NHS commissioning » Cancer (england.nhs.uk) england.npoc-cancer@nhs.net | |

5. Population and/or geography to be served

5.1 Population covered

This specification (the 'Specification') covers the provision of brachytherapy services ("the Service").

Brachytherapy is the treatment of disease with sealed radioactive sources which can be inserted either permanently into an organ, lesion or cavity or temporarily using interstitial needles or via an applicator using "afterloading" equipment. It can be used either as a standalone treatment or in combination with external beam radiotherapy. The service is a tertiary service and accessed only following referral from an appropriate tumour specific multidisciplinary team (MDT).

This Specification does not include the use of unsealed radioactive substances (such as injections or drinks) or external beam radiotherapy which are covered by separate service specifications.

5.2 Minimum population size

To ensure sufficient critical mass of infrastructure required to sustain the service including workforce, maintenance of professional expertise and regulatory compliance, the Service must be configured so that each centre offering the service delivers a total brachytherapy caseload that should exceed 50 cases per year as a minimum and meet the minimum annual case volume requirements for individual cancers and treatment type in line with RCR guidelines.

https://www.rcr.ac.uk/publication/role-and-development-afterloading-brachytherapy-services-united-kingdom.

Quality assurance practice guidelines for transperineal LDR permanent seed brachytherapy of prostate cancer (rcr.ac.uk)

At present, there is only one centre in England that is able to treat children with brachytherapy – it is expected that this will remain the case, in view of the overall expected activity volumes, clinical complexity and the need for close integration with other paediatric services (radiotherapy and paediatric oncology).

6. Service aims and outcomes

6.1 Service aims

The aims of the Service are to:

- Improve the outcomes from brachytherapy by delivering best practice treatments using appropriate technologies and holistic support in a safe and culturally appropriate way, enabling the diverse needs of service users to be met.
- Support disease specific multi-disciplinary teams to enable people requiring brachytherapy to access high-quality care at the right time and in the right place.
- Reduce variation in clinical practice through standardisation, audit, and the rapid adoption of best practice.
- Support the participation in clinical trials and research relating to conditions for which brachytherapy is considered suitable.

6.2 Outcomes

NHS Outcomes Framework Domains & Indicators

| Domain 1 | Preventing people from dying prematurely | |
|----------|--|--|
| Domain 2 | Enhancing quality of life for people with long-term conditions | |
| Domain 3 | Helping people to recover from episodes of ill-health or following injury | |
| Domain 4 | Ensuring people have a positive experience of care | |
| Domain 5 | Treating and caring for people in safe environment and protecting them from avoidable harm | |

Service defined outcomes/outputs

The quality of specialised services is monitored through Specialised Services Quality Dashboards (SSQDs), which normally comprise a range of quality outcomes (including clinical outcomes) and quality metrics which are supported by regular data collections. SSQDs are available on NHS England's website at: https://www.england.nhs.uk/specialised-commissioning-document-library/

Included in the range of metrics that support understanding of the quality of this service are:

| Metric Reference Number | Domain | Rationale | Name of Metric /Description |
|-------------------------------|---------|--|---|
| BRT01a | 1,2,4,5 | To assess maintenance of professional expertise and workforce sustainability | The number of episodes (adults) of brachytherapy that are carried out each year. |
| BRT01b | 1,2,4,5 | To assess maintenance of professional expertise and workforce sustainability | The number of brachytherapy episodes administered to paediatri service users (0-15 inclusive) that are carried out each year. |

7. Service description

7.1 Service Model

The Provider must ensure that the Service:

- Works as part of the Cancer Alliance in relation to the treatment of cancer with brachytherapy.
- Has agreed and documented network arrangements, protocols and associated clinical and referral pathways detailing that it can only be accessed by tertiary referral from an appropriate specialist clinician or multidisciplinary team (MDT).
- Has agreed local protocols in place to facilitate close collaboration and clear communication between members of the Service and the referring specialists/MDTs.
- Delivers treatment by multi professional teams including tumour specific surgeons where appropriate.
- Has a named Lead Clinician to provide effective clinical leadership to the Service.
- Works with other radiotherapy services within the network to ensure that commissioned brachytherapy treatments are offered to every service user, appropriate to their clinical circumstances and eligibility criteria set out within NHS England clinical commissioning policy.
- Has the capability to deliver treatment using combined intracavitary and interstitial techniques for the treatment of cervix cancer or has an established and agreed pathway to a centre where this can take place.
- Provides brachytherapy in a timely manner and in accordance with waiting time standards to all service users who require it (including urgent and palliative brachytherapy) as part of their treatment plan.
- Schedules treatment and integrates treatment appropriately to meet the service users' needs where brachytherapy is used concurrently with other treatments (such as external beam radiotherapy or chemotherapy).
- Ensures that appropriate consent is obtained, that both written and verbal information about the procedure prior to therapy, aftercare and follow-up

arrangements is provided to include the short and long-term side effects and minimising radiation exposure after discharge when appropriate.

- Has a robust system in place to monitor treatment outcomes.
- Implements new technologies that are recommended by the National Institute for Health and Care Excellence (NICE) and gives due regard to national clinical guidelines and guidance (Section 7.9).

For brachytherapy treatments delivered as part of a package of care that includes external beam radiotherapy delivered by another RT provider, the provider must:

- Have clear pathways, shared care arrangements and joint protocols in place to ensure continuity of patient care and support throughout the transition and post treatment.
- Define the clinical responsibilities of each team (e.g., radiotherapy department, nuclear medicine, radiology department) and individual specialists involved in aftercare and follow-up after brachytherapy treatment.

For brachytherapy treatments that are delivered outside of the oncology service (e.g., eye plaques), arrangements must be in place to ensure:

- that the decision to treat is agreed at an appropriate MDT (e.g., ocular oncology MDT).
- that appropriate referral pathways between the brachytherapy service and the treating surgical team are in place.
- the treating surgeon holds an Administration of Radioactive Substances Advisory Committee (ARSAC) practitioner license.

Where there is an "in-reach" model in place, i.e., where the Service utilises, clinical oncologists employed by other organisations to deliver brachytherapy from the Service's premises, the Provider must put in place an agreement that clearly defines:

- The cohort of service users to be treated by 'visiting' clinical oncologists.
- The arrangements describing the referral and MDT arrangements between the referring site and the treatment site.
- Explicit governance arrangements that include: the management of service users post Brachytherapy; discharge criteria; aftercare arrangements and defined clinical responsibilities to ensure continuity of patient care and support throughout the transition and post treatment.
- Where reciprocal arrangements are in place, the treating centre must ensure that robust arrangements are in place to ensure the continuity of patient care and support throughout the transition post treatment and transfer of care back to the referring centre.

The Provider must ensure that the Service operates in a clinically safe environment and:

 Ensures that all relevant ARSAC licenses are in place for employers and practitioners.

- Ensures that brachytherapy is administered by a practitioner with the appropriate ARSAC license or by another healthcare professional (HCP) (doctor, nurse, radiographer, scientist, or technologist) under delegated authority in line with the ARSAC notes for guidance and (Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) Legislation.
- Provides good patient care within a stringent clinical and operational governance frameworks.
- The service should meet the following case volume requirements per year in accordance with published standards (<u>The role and Development of afterloading Brachytherapy Services</u>)
 - Each clinical oncologist performs a minimum of 25 cases per year.
 - The intra-uterine applicator insertion is carried out by an appropriately trained clinical oncologist with relevant competencies and delivering a minimum of 10 insertions per clinician per year incorporating peer review (live or retrospective) in the contouring pathway in accordance with RCR
 Consensus statement.
 - Vault brachytherapy applicators may be inserted by appropriately trained clinicians, nurses, or radiographers after assessment by a specialist clinical oncologist and following assessment.
 - It is expected that each service will treat at least 10 patients per year using Interstitial HDR prostate brachytherapy to ensure that individual clinicians and physics staff have continued practical experience in accordance with RCR guidelines.
 - Deliver a minimum caseload of 50 per year per centre of Interstitial LDR prostate brachytherapy, with each oncologist performing 25 cases per year in order to maintain expertise. <u>DH guidelines</u> Gateway Reference 7385.
- Delivers brachytherapy in a well-equipped department with appropriate specialist support and is fully involved in the relevant MDTs that are responsible for planning multi-modality treatments.
- Engage with the Medical Physicist qualified to act as Medical Physics Expert in the field of brachytherapy and responsible for source and patient dosimetry, quality assurance programme, optimisation and safety of the treatment planning and assuring compliance with appropriate legislation and permits.)
- Ensures safe practice and adequate levels of equipment to deal effectively with medical emergencies.
- Handle radioactive sources in a safe designated area that meets statutory requirements.
- Ensures adequate precautionary measures to comply with relevant legislation and to ensure that radiation risks are minimised for staff, other workers, relatives, carers, and the general public.
- Conduct regular reviews to ensure that protocols remain up to date, and that staffing levels and skills mix are appropriate for the numbers of patients treated and for each type of treatment delivered.
- Manage all medicines and radiopharmaceutical products safely and securely, in accordance with local radiological rules, NHS Resolution and relevant consents and law. Legislation and Regulations that must be complied with are, as follows:
 - o Environmental Permitting Regulations (EPR) 2016.

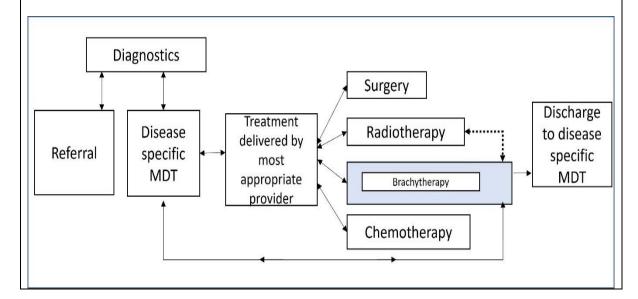
- Medicines Act 1968 (as amended).
- o Ionising Radiation (Medical Exposure) Regulations 2017 ("IR(ME)R") (as amended).
- The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009, as amended.
- Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) ("ADR Agreement").
- The Ionising Radiations Regulations 2017.
- Have contingency plans in place to deal with the following:
 - Adverse reactions and adverse incidents.
 - o Clinical issues not related to brachytherapy.
 - o Reasonably foreseeable accidents involving radioactive materials.
 - Referrals outside routine pathways (e.g., reciprocal arrangements with another centre) that ensure continuity of patient care and support throughout the transition and post treatment as per regular pathways.
- Participate in the national inter-departmental dosimetry audit programmes.
- Collect and submit data to the mandated national radiotherapy dataset (RTDS) according to national requirement.
- Record local recurrence and survival and toxicity data and carry out audit that regularly to increase local knowledge on treatment outcomes.

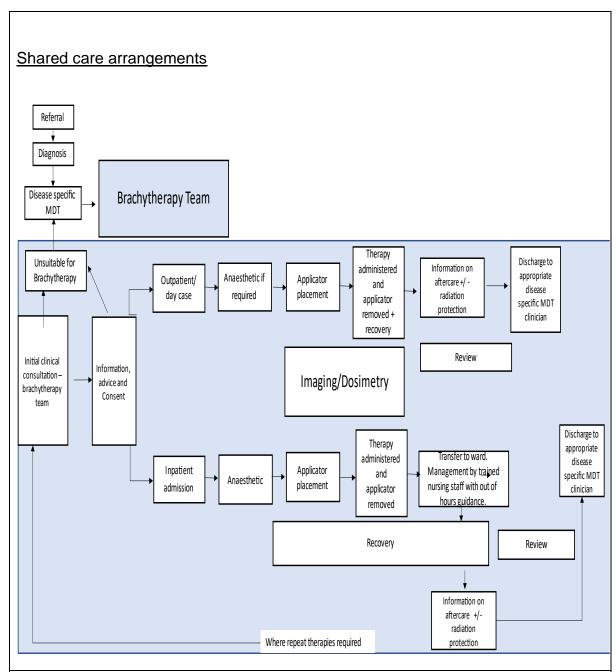
Where the Service delivers brachytherapy to children:

The Service must be delivered in line with the Royal College of Radiologists (RCR) 'Good practice guide for paediatric radiotherapy.' In view of the low activity volumes and complexity associated with treating children with brachytherapy, it must be delivered at a designated paediatric radiotherapy centre working as part of a Children's Cancer Principal Treatment Centre and its associated subspecialist paediatric cancer MDTs. The Service must have the appropriate brachytherapy expertise, staffing and facilities for the treatment of children.

7.2 Pathways

Overall patient pathway





7.3 Clinical Networks

There is a requirement for providers of this service to comply with the provisions of Schedule 2F (Clinical Networks) of the NHS Standard Contract 2022/23 The Particulars. This includes meeting the requirements of the relevant Specialised Services Clinical Network Specification.

| Clinical Network/ODN | Link to 'published' network/ODN specification | |
|----------------------|---|--|
| Children's Cancer | 1746-principal-treatment-centres-service- | |
| Network | specification | |
| Teenage and | Teenage and young adult cancer clinical network | |
| Young Adult Cancer | specification | |
| Network | NHS England » Teenage and young adult cancer | |
| | clinical network specification | |

| Radiotherapy Network | Operational-Delivery-Networks-for-External-Beam- |
|----------------------|---|
| | Radiotherapy-Services-adults.pdf (england.nhs.uk) |
| | |

7.4 Essential Staff Groups

The Provider must ensure that the service has sufficient, appropriately trained staff to meet activity and deliver safe and effective brachytherapy service. Contingency arrangements must be agreed across a Network footprint to ensure that reciprocal arrangements are in place where the minimum staffing requirements cannot be met.

The brachytherapy team should include at least:

- Two clinical oncologists with brachytherapy expertise in each disease type being treated by the Service.
- Three physicists, two of which need to be Medical Physics Experts (MPEs) in brachytherapy.
- Three radiographers with brachytherapy competence.

With access to:

- Anaesthetists.
- Theatre team.
- Radiologists.
- Radiation Protection Advisers
- Tumour specific surgeons, where appropriate.

Where delivering paediatric brachytherapy, the Provider must also ensure that the Service has access to:

- Paediatric clinical oncologists working in close association with brachytherapy subspecialists.
- Therapeutic radiographers with specialist brachytherapy expertise.
- Experienced health play specialists, as required, that are able to meet local service needs and undertake an initial assessment as to whether brachytherapy without anaesthesia is possible.

7.5 Essential equipment and/or facilities

The Provider must ensure that the Service has access to:

- Appropriately staffed operating theatre and/or brachytherapy suite with operating facilities.
- Anaesthesia.
- Recovery.
- Planning systems +/-treatment afterloading system.
- Planning system.
- Appropriate source storage and handling in accordance with national guidance.
- Applicators/needles/templates for each tumour site being treated.
- Suitable access to appropriate imaging facilities.
- Appropriate equipment for quality assurance.

Where delivering paediatric brachytherapy, the Provider must also ensure that the Service has access to:

- A specialist paediatric anaesthetic service.
- On-site paediatric resuscitation.
- Appropriate overnight accommodation.
- Mandatory age specific support services.

7.6 Inter-dependant Service Components – Links with other NHS services

| Interdependent Service | Relevant Service Specification/Standards | Proximity to service (not applicable/co- located/same town/city) |
|---|---|---|
| CT / MRI Imaging | N/A | Co-located |
| Nuclear medicine Imaging (PET-CT and SPECT-CT) | TBC | N/A |
| Children's Cancer Principal Treatment Centre | ren's Cancer Children's Cancer Network - Same town (Co-locate ment - 1746-principal-treatment services | |
| Teenage and Young Adult Cancer Services | Specialist cancer services for children and young people: teenage and young adults principal treatment centre services NHS England » Specialist cancer services for children and young people: teenage and young adults principal treatment centre services NHS England » Specialist cancer services NHS England » Specialist cancer services for children and young people: teenage and young adults designated hospitals NHS England » Teenage and young adults designated hospitals | Not applicable |
| Adult Radiotherapy Service | Adult Radiotherapy Services 170091S External-Beam- Radiotherapy-Services-Delivered- as-Part-of-a-Radiotherapy- Network-Adults.pdf (england.nhs.uk) | Co-located |

| Paediatric Photon Radiotherapy Services Sub-heading: Paediatric Photon External Beam Radiotherapy Services | 230601-paediatric-photon- radiotherapy-service- specification.pdf (england.nhs.uk) | Co-located |
|--|--|----------------|
| Anaesthesia | Guidelines for the Provision of Paediatric Anaesthesia Services 2020. GPAS-2020-10-PAEDIATRICS.pdf (rcoa.ac.uk) | Same town/city |
| Proton Beam Therapy | 170012/S - Proton Beam Therapy Service (Adults and Children) - proton-beam-therapy-service.pdf (england.nhs.uk) | Not applicable |

7.7 Additional requirements

Not applicable.

7.8 Commissioned providers

The list of commissioned providers for the services covered by this specification are as follows: [ADD LINK TO THE COMMISSIONED PROVIDER LIST ONCE AVAILABLE]

7.9 Links to other key documents

Please refer to the <u>Prescribed Specialised Services Manual</u> for information on how the services covered by this specification are commissioned and contracted for.

Please refer to the <u>Identification Rules</u> tool for information on how the activity associated with the service is identified and paid for.

Please refer to the relevant Clinical Reference Group <u>webpages</u> for NHS England Commissioning Policies which define access to a service for a particular group of service users. The specific clinical policies that relate to the services covered by this service specification include:

 Brachytherapy dose escalation with external beam radiotherapy for intermediate and high-risk localised prostate cancer https://www.england.nhs.uk/publication/brachytherapy-dose-escalation-with-external-beam-radiotherapy-for-intermediate-and-high-risk-localised-prostate-cancer/

Relevant National and Professional Guidance

 Gynaecological cancer: RCR consensus statements | The Royal College of Radiologists

- Advice on the development of Permanent Seed Implant Brachytherapy Services (low dose brachytherapy) for localised prostate cancer in England. The DH guidelines Department of Health Gateway Reference 7385.
- Quality Assurance Practice Guidelines for Transperineal LDR permanent seed brachytherapy of prostate cancer.
 Quality assurance practice guidelines for transperineal LDR permanent seed brachytherapy of prostate cancer (rcr.ac.uk)
- The role and development of afterloading brachytherapy services in the United Kingdom (2012) https://www.rcr.ac.uk/publication/role-and-development-afterloading-brachytherapy-services-united-kingdom
- RCR Good Practice guide for paediatric radiotherapy https://www.rcr.ac.uk/publication/good-practice-guide-paediatric-radiotherapy-second-edition

Relevant NICE Guidance

- https://www.nice.org.uk/guidance/ipg531
- https://www.nice.org.uk/guidance/ipg132
- https://www.nice.org.uk/guidance/ipg160
- https://www.nice.org.uk/guidance/ipg415
- https://www.nice.org.uk/guidance/ipg268
- https://www.nice.org.uk/guidance/ipg174
- https://www.nice.org.uk/guidance/ipg532
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