#### **SCHEDULE 2 – THE SERVICES**

# A. Service Specifications

1.	Service name	Stereotactic Radiosurgery and Stereotactic Radiotherapy (Intracranial) (All Ages) Subspecialisation – SRS/SRT All indications
2.	Service specification number	2324
3.	Date published	September 2024
4.	Accountable Commissioner	NHS England – Cancer National Programme of Care (NPOC) NHS commissioning » Cancer (england.nhs.uk)

## 5. Population and/or geography to be served

## 5.1 Population Covered

This Service Specification (the "Specification") relates to the provision of the stereotactic radiosurgery (SRS), (delivered in a single treatment) or stereotactic radiotherapy (SRT) (delivered in 2 to 5 daily treatments) service (the "Service"). The Specification covers the complete range of intracranial conditions as set out within NHS England clinical commissioning policy comprising:

- Tier 1 and Tier 2 indications of cerebral metastases, non-skull base meningiomas, skull base tumours, including vestibular schwannoma, and meningioma, pituitary adenoma; and
- Tier 3 and Tier 4 indications, including arteriovenous malformations, trigeminal neuralgia and paediatric CNS tumours.

#### 5.2 Minimum population size

The Service must be delivered as part of an integrated neurosurgical and oncology service located within the same geographical area or city. The neurosurgical centre must host the full range of specialist intracranial multi-disciplinary teams (MDTs) for all clinical indications for adult and paediatric intracranial tumours, namely, combined Neurosciences Brain and Central Nervous System (CNS) MDT, and / or the individual neuro-oncology MDTs, skull base MDT, and pituitary MDT, neuro-vascular MDT and paediatric oncology MDTs as listed in Table 1, to generate a minimum annual activity volume of: (i) 100 SRS/SRT Tier 1 and Tier 2 cases; plus (ii) circa 200 Tier 3 and Tier 4 (combined) cases. It is expected that this will result in up to four All Tiers services, including paediatric oncology services, covering the geography of England, which will generate sufficient volume to ensure service sustainability including workforce and maintain professional expertise. To generate 100 Tier 1 and Tier 2 SRS/SRT cases per year, the service will require a neurosurgical population of at least 2 million.

#### 6. Service aims and outcomes

#### 6.1 Service aims.

The aim of the Service is to:

- Improve life expectancy and quality of life for Service Users requiring SRS/SRT by delivering best practice treatments, using appropriate technologies and holistic support in a culturally appropriate way enabling the diverse needs of Service users to be met.
- Ensure adults, children and young people requiring SRS/SRT have access to high-quality care at the right time and in the right place, delivered by an appropriately trained and experienced multi-professional specialist workforce.
- Reduce variation in clinical practice through standardisation, audit, and the rapid adoption of best practice.

 Support participation in clinical trials and research relating to brain tumours and benign intracranial conditions.

## 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	<b>✓</b>

# 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: <a href="https://www.england.nhs.uk/specialised-commissioning-document-library/">https://www.england.nhs.uk/specialised-commissioning-document-library/</a>

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

Outcome Reference Number	Domain	Rationale	Name of Outcomes/Description
05a	1,3		Percentage mortality within 30 days following SRS/SRT treatment for cerebral metastases
05b	1,3		Percentage mortality within 30 days following SRS/SRT treatment (excluding cerebral metastases)
07a	1, 4, 5	To assess appropriate patient selection for SRS/SRT.	Percentage of patients with malignant disease alive at 6 months post SRS/SRT
07b	1, 4, 5	To assess appropriate patient selection for SRS/SRT.	Percentage of patients with malignant disease alive at 12 months post SRS/SRT

## 7. Service description

### 7.1 Service model

The Provider must work closely with the local Cancer Alliance(s) to ensure effective service planning and pathway integration of the Service.

## The provider must ensure that the SRS/SRT Service:

 Is delivered as part of an integrated neurosurgical and oncology service located within the same geographical area or city and co-located with a full skull-base team and vascular team.

- Delivers the complete range of SRS/SRT treatments (Tiers 1-4), Table 1 and participates in the full range of specialist neurosurgical MDTs.
- Operates in accordance with MDT arrangements, referral criteria and pathways, clinical protocols, policies, and treatment pathways (including palliative care and end of life care).
   This must include clarity about the roles and responsibilities of all providers and partners across the SRS/SRT pathway.
- Builds referral networks with all referring teams within the geography covered to ensure optimal access to treatment for eligible service users. This includes engaging with referring teams to share information on patient eligibility criteria, referral pathways and patient outcomes.
- Provides resilience and experience to Tier 1 and Tier 2 services within the broader geography supporting the referral and treatment of complex cases as required.
- Has robust continuity and contingency plans in place to ensure that access to SRS/SRT is routinely available as a treatment option for eligible for patients at times of upgrade, source change and/or machine replacement and in accordance with the Adult Radiotherapy Service Specification.
- Implements new technologies as recommended by the National Institute for Health and Care Excellence (NICE) and gives due regard to national clinical guidelines and guidance (Section 7.9).
- Gives due regard to other national guidance, including: relevant rapid cancer diagnostic
  and assessment pathways, optimal timed pathways (<u>NHS England » Faster diagnosis</u>),
  personalised care and improving quality of life outcomes (<u>NHS England » Personalised
  care and improving quality of life outcomes</u>) and elective recovery programmes, such as
  Outpatient Recovery and Transformation.
- Operates 52 weeks per year the Service is a tertiary service, accessed by referral from an appropriate Consultant who is a member of an appropriate disease-group-specific MDT.

Where the Service is delivering SRS/SRT treatment for paediatric intracranial cancer, the Provider must deliver the Service as part of an integrated paediatric neurosurgical and oncology service, commissioned to provide Paediatric Photon Radiotherapy located within the same geographical area or city to a Children's Cancer Principal Treatment Centre (PTC) with access to:

- Access to an experienced paediatric and SRS/SRT subspecialist Clinical Oncologist.
- Direct access to the mandatory age specific support services and established tertiary paediatric neuro-oncology MDTs.

To note: Paediatric service users with either neurofibromatosis type 2 (NF2) associated tumours or arteriovenous malformation (AVMs) will remain within the current framework of commissioned services for adults as here the technical expertise of the supra-network SRS MDT is perceived to be of higher importance than the specific primary paediatric tumour site expertise.

#### **Table1: The Clinical Model**

Tier 1 activity (neuro-	Deemed to be of lower complexity. This includes cerebral	
oncology)	metastases and non-skull base meningiomas and follows the	
	patient pathway for patients via a regional adult neuroscience	
	(neuro-oncology) MDT and in conjunction with Teenage and	
	Young Adult (TYA) MDTs and pathways.	
Tier 2 activity (skull-base	Includes tumours such as vestibular schwannoma,	
& pituitary)	meningioma, etc requiring co-location with a full skull-base	
' ''	team and following the patient pathway via a regional (adult)	
	skull-base MDT in a neurosurgical centre. Pituitary (adult)	

Paediatric CNS Tumours	indications require full pituitary MDT. Together with tier one this should allow >100 procedures per year, per delivery site.  Subset of CNS Tumours including local recurrence or cranial metastatic CNS tumours and brain metastases from solid tumours	
Tier 3 activity (Vascular)	Includes cases such as Cerebral Arteriovenous Malformations and cavernomas. Requiring co-location with a full vascular MDT and full imaging support services, such as Digital Subtraction Angiography	
Tier 4 activity (other non-tumour indications)	Includes trigeminal neuralgia. Lower volume; best carried out in fewer centres, enabling appropriate staffing skill-mix, MDT support, co-located services, and appropriate equipment. Requires co-location of relevant MDTs – functional, epilepsy, pain services	

NB. Cases approved via the Individual Funding Request (IFR) process for any other indication including "lesioning" for movement disorders, epilepsy, and pain, must be managed as part of Tier 4.

#### The Provider must ensure that the Service:

- Has completed all pre-assessment external Radiotherapy Quality Assurance requirements and is accredited to deliver SRS/SRT treatment as required by NHSE in order to treat Service users.
- Has a named lead clinician who is responsible for providing effective clinical leadership to the SRS/SRT service.
- Has a named neurosurgical lead who is responsible for the care of patients requiring Tier 3 & Tier 4 indications.
- Has a regular SRS/SRT team meeting that supports multi-disciplinary discussion of each
  case during the planning and treatment phases of the care pathway either alongside, in
  parallel or separately with appropriate neurosurgical MDTs, providing there is full
  representation of core members, including a neurosurgeon and neuroradiologist and,
  when appropriate, specialists in the management of TYAs.

Where a service is delivering Tier 1 & Tier 2 SRS activity in partnership with another neurosurgical service and SRS/SRT team and out of more than one geographical site, the Provider must evidence an agreement in place that clearly defines:

- The cohort and number of patients to be treated at each delivery site and treatment platform.
- The arrangements describing the fully functional MDT arrangements in place at both sites.
- The arrangements to ensure that each delivery site delivers a minimum of 100 cases per year.
- The joint service will submit a single set of national returns, such as contract and data monitoring, quality, and performance.

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

Radiotherapy is delivered in a well-equipped department using one of several technologies including Gamma Knife, Cyberknife, Zap-X and linear accelerator-based technology (LINAC) and modified to enable appropriate beam collimation to deliver accurate treatment with high conformity and steep dose gradient as described in the <a href="ISRS certification">ISRS certification</a> standard.

- Treatment planning and delivery is optimised using clinically commissioned beams down to less than or equal to 4mm width with treatment planning modulation capable to conformally treat small volume lesions equal to 0.02cc as demonstrated by Paddick et al.
- Protocols are in place to verify dosimetric accuracy and geographical accuracy of treatment, to include imaging, end to end tests and patient movement management to minimise uncertainties of treatment of ≤1.0mm as described in the <u>ISRS certification</u> standards.
- The consequent "whole body dose" is kept to a minimum for children, TYAs and adults under the age of 40 as they have the greatest lifetime risk of developing a tumour as a sequalae of radiation treatment. Radiation Risks from Medical X-ray Examinations as a Function of the Age and Sex of the Patient (publishing.service.gov.uk)
- The service must be aware of the dose delivered by each machine used to treat SRS
  patients measured at 30cm inferior to the target using either using either
  an anthropomorphic phantom or in vivo dosimetry or equivalent as a baseline
  measurement using clinically representative scenarios as benchmarks. Specifically:
  - For children (0-16th birthday) regardless of clinical indication the point dose measurement must be kept below 6mGy at a representative reference distance of 30cm inferior to the target.
  - For TYA regardless of clinical indication and Adults up to age 40 with benign disease
    the point dose measurement must be no greater than 20mGy at a presentative
    reference distance of 30cm inferior to the target.
- Treatments are delivered in a safe and effective way and that robust audit mechanisms are in place to monitor treatment outcomes and continuously monitor service risks using a governance approach that includes:
  - Strong clinical and operational governance arrangements of the Service are in place.
  - Quarterly clinical audit and service review meetings to cover as a minimum: (i)
    performance and quality outcomes; (ii) casemix; (iii) audit of treatments; (iv) Protocols
    and policies; (v) critical incidents and near misses; and (vi) review of deaths within 30
    days of treatment are in place.
- All patients are provided with detailed information booklets and relevant website
  addresses and have access to a specialist nurse, specialist therapeutic radiographer or
  keyworker throughout the referral and treatment process.
- Consent or other valid authority, including pregnancy status from the age of 12 onwards, is obtained before any examination or investigation, provide treatment, or the involvement in teaching or research.
- Legislation and Regulations are complied with including the Ionising Radiation (Medical Exposure) Regulations 2017 ("IR(ME)R") (as amended).

# Service users must receive care delivered by subspecialist SRS/SRT neurosurgeons and SRS/SRT neuro-oncologists working closely with neuro-radiologists that:

- Are integrated within the full range of specialist MDTs hosted at the neurosurgical centre / PTC and the full SRS/SRT clinical treatment team with explicit referral arrangements in place to refer and work jointly with the SRS/SRT MDT.
- Are involved in the decision to refer to the SRS/SRT MDT prior to the referral being made and the SRS/SRT MDT accepting the patient for treatment.
- Are integrated as part of the assessment service to include the necessary tumour site specific expertise (brain and spine) and oncological expertise to determine the suitability of individual cases for SRS/SRT.
- Advise on case selection to ensure all treatment options are considered and plan and supervise the treatment and ensure that consent is formally documented.
- Take responsibility for ensuring referrals from outside of their own catchment also have been through local MDTs and that all other treatment options have been considered.

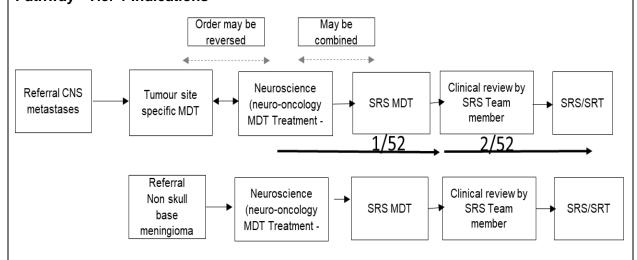
- Communicate the diagnosis and management plan to the referring consultant/MDT and the General Practitioner (GP) within 2 days of the definitive management plan being established.
- Ensure that clinical review for patients with malignant disease takes place within 1 week of the Neurosciences (Neuro-oncology) MDT meeting.
- Ensure that treatment with SRS for patients with malignant disease is delivered within 2 weeks of decision to treat (in clinic).
- Has a process and pathway in place for post treatment follow up to ensure either discharge back to the referring consultant/specialist MDT following treatment or follow up by the SRS MDT.
- Take responsibility for the follow up plan including the management of late effects and survivorship.
- Offer continuous staff education and training to demonstrate competence at Tier 3 and Tier 4
- Participate in relevant clinical trials/ studies with support from the clinical trials team to maximise recruitment into relevant studies.

### 7.2 Pathways

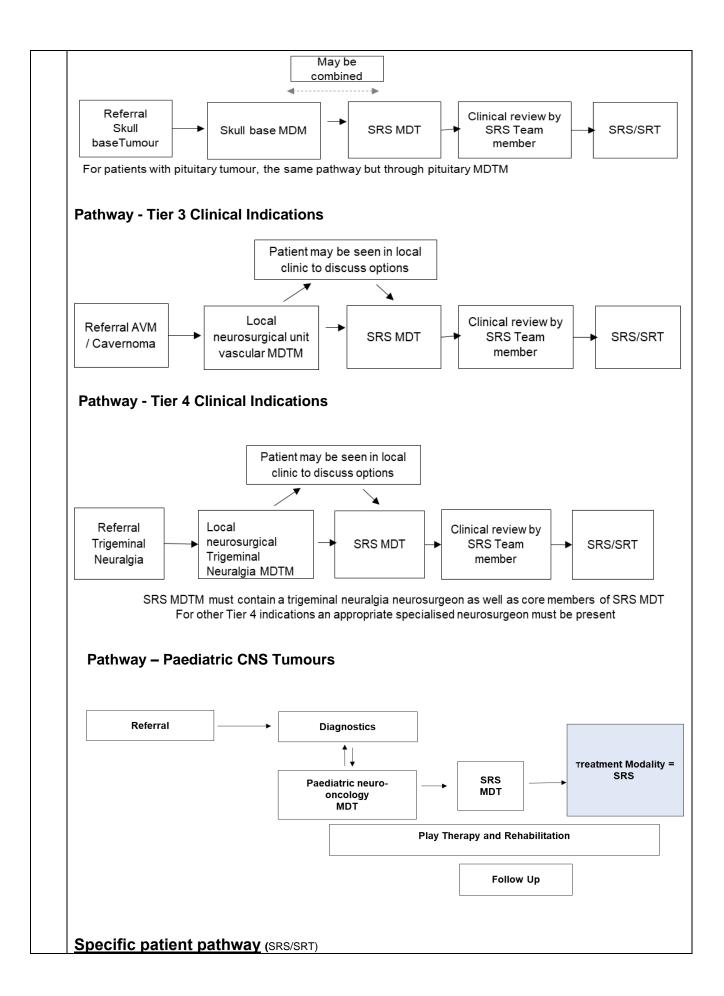
#### Overall patient pathway

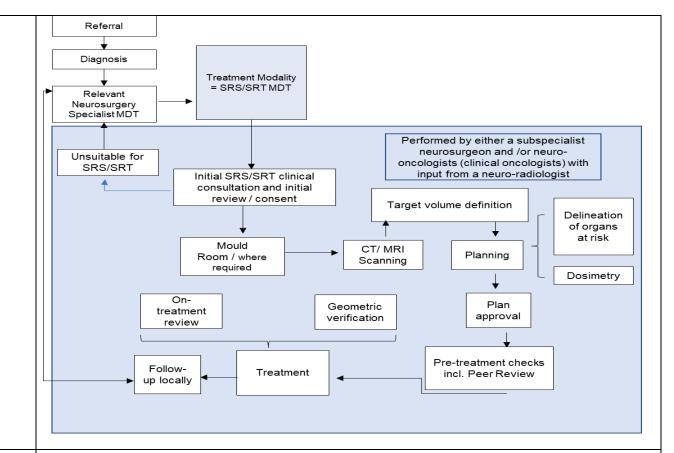
- The decision to refer a patient to the SRS/SRT MDT is made by the appropriate subspecialist MDT as described below:
  - Cerebral metastases to a Neurosciences Brain and Central Nervous System (CNS) (neuro-oncology) MDT are made by (or in conjunction with) a disease-specialist MDT which must consider the role of active management of brain metastases with SRS or surgery within the patient's overall oncological management and prognosis.
  - o Indications other than brain metastases, will be made by the appropriate subspecialist MDT e.g., oncology, skull base MDT or pituitary MDT.
  - Vascular and other non-cancer conditions, the decision to offer SRS/SRT is made by the appropriate sub-specialist MDT e.g., the neuro-vascular MDT, before referral.
  - Paediatric neuro-oncology, the decision to offer SRS/SRT will be made by the appropriate sub-specialist MDT.
  - Any referral deemed ineligible for SRS/SRT treatment by the SRS MDT on clinical grounds, is conveyed to the patient by the referring consultant,

#### Pathway - Tier 1 Indications



#### Pathway - Tier 2 Clinical Indications





### 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 ODN	Link to 'published' network/ODN specification
Neurosurgery Networks	TBC
Children's Cancer	1746-principal-treatment-centres-service-specification
Teenage and Young Adults	NHS England » Teenage and young adult cancer clinical network specification
Radiotherapy Operational Delivery Networks	Operational-Delivery-Networks-External-Beam-Radiotherapy-Services-adults

## 7.4 Essential Staff Groups

- Expertise in intracranial stereotactic radiosurgery requires added competence for Neurosurgeons and Oncologists.
- The Provider must demonstrate appropriate specialist training in SRS/SRT beyond equipment-specific practical training and ensure sufficient throughput to maintain competence.
- The staff involved must be appropriately trained, competent and have the experience required in order to meet the requirements of Ionising Radiation (Medical Exposure) Regulations 2017 ("IR(ME)R") (as amended).

- The following disciplines with training and expertise in intracranial stereotactic radiosurgery must form the core part of the dedicated and experienced SRS/SRT Treatment and Planning Team:
  - Neuro-oncologists
  - Neurosurgeons.
  - Neuro-radiologists.
  - SRS/SRT Medical physics experts, dosimetrists and physicists and Health technology staff.
  - All treatments will be delivered by specialist therapeutic radiographers trained to operate SRS/SRT treatment platforms.
  - o Clinical nurse specialists.
  - Administrative support.
  - Specialist paediatric and TYA staff as required.

# 7.5 Essential equipment and/or facilities

#### **Providers MUST ensure that:**

- SRS/SRT treatments are only delivered using a treatment platform that has completed the national NPL SRS audit. This audit will be repeated during 2024/25 for 1 machine per delivery site.
- Should additional or replacement machines be required providers MUST ensure that a successful NPL audit is completed in advance of treating patients at their own cost.

#### Providers must have access to:

- Interventional Radiology services for the treatment of Arteriovenous Malformations and be able to transport patients safely from these services to the SRS/SRT treatment area.
- Dedicated vascular services (level 3).
- General anaesthesia for patients unable to lie still for the procedure due to other conditions.

# When treating children, have access to:

- Specialist paediatric anaesthetic service and a dedicated are including on-site paediatric
  resuscitation, life support teams immediately available and appropriate overnight
  accommodation and the mandatory age specific support services and environment. This
  should be in keeping with the Good Practice Guide for Paediatric Radiotherapy.
- Experienced health play specialists, as required, that are able to cover the local service needs and undertake an initial assessment as to whether SRS/SRT without anaesthesia is possible.

# 7.6 Interdependent Service Components – Links with other NHS services

Interdependent SRS/SRT Service – All	Relevant Service Specification/Standards	Proximity to service
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
Adult Neurosurgery	NHS commissioning » D04. Neurosciences (england.nhs.uk)	Same town / city

Teenage and Young adults Principal Treatment Centre	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 for children and young people: teenage and young adults designated hospitals	Same town / city
Vascular Disease	NHS commissioning » A04. Vascular Disease (england.nhs.uk)	Same town/city
Children's Cancer Principal Treatment Centre	Children's Cancer Network - Principal Treatment Centres - 1746-principal- treatment-centres-service-specificationpdf (england.nhs.uk)	Same town/city
Children's Radiotherapy	230601-paediatric-photon-radiotherapy- service-specification.pdf (england.nhs.uk)	Co-located
Paediatric Neurosurgery	NHS commissioning » E04. Paediatric Neurosciences (england.nhs.uk)	Same town/city
Anaesthesia	Guidelines for the Provision of Paediatric Anaesthesia Services 2020. <u>GPAS-2020-</u> 10-PAEDIATRICS.pdf (rcoa.ac.uk)	Co-located
Intensive Care	Paediatric Intensive Care. <a href="https://www.england.nhs.uk/commissioning/spec-services/npc-crg/group-e/e07/">https://www.england.nhs.uk/commissioning/spec-services/npc-crg/group-e/e07/</a>	Same town/city
Neurorehabilitation	E09/S/d Paediatric Neurorehabilitation Paediatric-Neurorehabilitation.pdf (england.nhs.uk)	Same town/city
Proton Beam Therapy	170012/S - Proton Beam Therapy Service (Adults and Children) - proton-beam-therapy-service.pdf (england.nhs.uk)	National
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# 7.7 Additional requirements

## **SRS/SRT providers must:**

Have an externally accredited quality management system in place, in accordance with the requirements of *Towards Safer Radiotherapy (Royal College of Radiologists et al, 2008)*.

- Ensure that data is made available for effective peer review of target volumes.
   <a href="https://www.rcr.ac.uk/publication/RT-target-definition-peer-review">https://www.rcr.ac.uk/publication/RT-target-definition-peer-review</a>
- Ensure that a method, which is independent of the planning computer and independent of the person producing the computer-generated plan, is in place for checking the monitor unit calculation/treatment times, *Towards Safer Radiotherapy* (Royal College of Radiologists et al, 2008);
  - https://www.rcr.ac.uk/sites/default/files/publication/Towards\_saferRT\_final.pdf
- Drive improvement in the delivery of SRS/SRT services in line with ISRS\_certification\_standards\_New\_Logo.pdf (isrsy.org)

https://www.practicalradonc.org/article/S1879-8500(23)00161-3/fulltext

Submit to the mandated national radiotherapy dataset (RTDS).

# 7.8 Commissioned providers

The list of commissioned providers for the services covered by this specification can be found here. [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 Identification Rules tool for information on how the activity associated with the service is identified and paid for.

## Relevant NICE Guidance (exc. Technology Appraisals)

- Improving Outcomes for People with Brain and Other CNS Tumours <a href="https://www.nice.org.uk/guidance/csg10/resources/improving-outcomes-for-people-with-brain-and-other-central-nervous-system-tumours-update-pdf-27841361437">https://www.nice.org.uk/guidance/csg10/resources/improving-outcomes-for-people-with-brain-and-other-central-nervous-system-tumours-update-pdf-27841361437</a>
- NICE Quality Standard Topic Overview Brain tumours (primary) and brain metastases in adults. https://www.nice.org.uk/guidance/qs203/documents/topic-overview-2
- NICE Interventional Procedure Guidance Trigeminal Neuralgia (http://guidance.nice.org.uk/IPG85)
- Brain tumours (primary) and brain metastases in over 16s https://www.nice.org.uk/guidance/ng99/chapter/recommendations

The Provider must also ensure that the Service is delivered in accordance with all relevant NHS England clinical commissioning policy which define access to a service for a particular group of service users. The specific clinical policies that relate to the services covered by the Specification can be found at: <a href="NHS commissioning">NHS commissioning</a> » Radiotherapy (england.nhs.uk) and include:

- Stereotactic radiosurgery and radiotherapy for pituitary adenomas (RC)
- <u>Stereotactic radiosurgery (SRS) and stereotactic radiotherapy (SRT) to the surgical cavity following resection of cerebral metastases (All ages)</u>
- Stereotactic Radiosurgery/Stereotactic Radiotherapy for Cerebral Metastases
- <u>Stereotactic radiosurgery/radiotherapy for ependymoma, haemangioblastoma, pilocytic astrocytoma and trigeminal schwannoma</u>
- Stereotactic radiosurgery (SRS) for adults with Parkinson's tremor and familial essential tremor
- <a href="https://www.england.nhs.uk/wp-content/uploads/2018/11/stereotactic-radiosurgery-and-stereotactic-radiotherapy-intracranial-ependymoma-children.pdf">https://www.england.nhs.uk/wp-content/uploads/2018/11/stereotactic-radiosurgery-and-stereotactic-radiotherapy-intracranial-ependymoma-children.pdf</a>
- Clinical Commissioning Policy Statement Stereotactic Radiosurgery and Stereotactic Radiotherapy for Primary Non-Germ Cell Pineal Tumours (All Ages) (england.nhs.uk)