Integrated Impact Assessment Report for Clinical Commissioning Policies

Policy Reference Number	1603		
Policy Title	Stereotactic radiosurgery/ radiotherapy for the treatment of pituitary adenomas [Adults]		
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Sections A – C	
Theme / Questions: Each section is divided into themes. Each theme sets out a number of questions.	**Responses / Comments:** All questions are answered by selecting a drop down option or including free text in line with the specified word limit. Data in this document is either drawn from one of the relevant policy documents or a source for the information is provided. Where assumptions are included where data is not available, this is specified.
Section A - Activity Impact	
A1 Current Patient Population & Demography / Growth	
A1.1 Prevalence of the disease/condition.	There are two types of pituitary adenomas – non-functioning and functioning. **Non-functioning pituitary adenomas** have a prevalence rate of 22.2 per 100,000. There are three types of **functioning adenomas**, 1. prolactinomas, which have a prevalence rate of 44.4 per 100,000, 2. Growth Hormone (GH) secreting pituitary adenomas prevalence rate of 8.6 per 100,000, 3. Adrenocorticotrophic Hormone (ACTH) secreting pituitary adenomas prevalence 1.2 per 100,000 *Source: Policy Proposition section 6*

A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria.	400 per year *Source: Policy proposition section 6*
A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria.	**Adults**
A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria	Not applicable.
A1.5 How is the population currently distributed geographically?	**Evenly** This is in line with the national procurement process undertaken by NHS England in 2015/16. There are 16 SRS/SRT contracted providers treating these patients currently. *Source: Policy Proposition section 6*
A2 Future Patient Population & Demography	
A2.1 Projected changes in the disease/condition epidemiology, such as incidence or prevalence (prior to applying the new policy) in 2, 5, and 10 years?	**Constant** In 2015/16 provider data confirmed that 103 patients were treated using SRS/SRT and estimates indicate that in 2016/17 116 patients were treated using SRS/SRT. It is estimated that up to 400 patients per year will be eligible for SRS/SRT. The increase in the number of patients eligible for the treatment is due to a clearer

<table>
<tr><td></td><td>definition of the eligibility criteria and the patient pathway compared to the current commissioning statement. The underlying number of patients with these tumour types is not increasing.
Source: Policy Proposition section 6</td></tr>
<tr><td>A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?</td><td><u>No</u>
Source: Policy Proposition section 6/other</td></tr>
<tr><td>A2.3 Expected net increase or decrease in the number of patients who will be eligible for treatment, according to the proposed policy commissioning criteria, per year in years 2-5 and 10?</td><td><table><tr><td>YR2 +/-</td><td>+6</td></tr><tr><td>YR3 +/-</td><td>+9</td></tr><tr><td>YR4 +/-</td><td>+11</td></tr><tr><td>YR5 +/-</td><td>+13</td></tr><tr><td>YR10 +/-</td><td>+27</td></tr></table>Source: Policy Proposition section 6/ other.
This is based on a needs assessment undertaken in 2015/16 to inform the national procurement of SRS/SRT services.</td></tr>
</table>

A3 Activity	
A3.1 What is the purpose of new policy?	**<u>Revise existing policy statement</u>**

A3.2 What is the annual activity associated with the existing pathway for the eligible population?	400 *Source: Provider data 2015/16*
A3.3 What is the estimated annual activity associated with the proposed policy proposition pathway for the eligible population?	400 *Source: Needs Assessment undertaken in 2015/16 to inform national SRS/SRT service procurement.*
A3.4 What is the estimated annual activity associated with the next best alternative comparator pathway for the eligible population?	1100 The majority of pituitary adenomas will be first treated with surgery. However, sometimes it is not possible to remove the whole tumour with surgery, this means that some of the tumour cells are left behind which is called 'residual tumour'. There are currently three treatment options for patients with residual and recurrent pituitary adenomas: further surgery; Conventional RT, SRS/SRT and medcal treatments. Some of these patients with residual tumour may be treated using conventional radiotherapy or SRS/SRT. In addition, sometimes the tumour can return following surgical treatment, this is called 'recurrent tumour'. These patients are currently treated using conventional RT / surgery or SRS/SRT. *Source: Policy working group*

A4 Existing Patient Pathway	
A4.1 **Existing pathway:** Describe the relevant currently routinely commissioned: • Treatment or intervention • Patient pathway • Eligibility and/or uptake estimates.	SRS/SRT is routinely commissioned in these indications via the existing policy statement. *Source: Published clinical commissioning policy statement*
A4.2. What are the current treatment access and stopping criteria?	Stereotactic Radiosurgery Not suitable for open surgery OR for residual or recurrent pituitary lesions that have undergone maximal safe surgical resection and/or radiotherapy, that are less than 4 cm^3, and are more than 3 mm away from the optic apparatus [ii] AND / OR Extension of the tumour into the cavernous sinus Stereotactic Radiotherapy: Inability to achieve radiation to optic apparatus within dose tolerance with radiosurgery *Source: Published clinical commissioning policy statement*
A4.3 What percentage of the total eligible population is expected to: a) Be clinically assessed for treatment b) Be considered to meet an exclusion criteria following assessment c) Choose to initiate treatment d) Comply with treatment	a) 100% b) 100% c) 100% d) 100%

e) Complete treatment?	e) 100% *Source: Policy working group*
A5 Comparator (next best alternative treatment) Patient Pathway	
A5.1 **Next best comparator**: Is there another 'next best' alternative treatment which is a relevant comparator? *If yes, describe relevant* • *Treatment or intervention* • *Patient pathway* • *Actual or estimated eligibility and uptake*	**<u>Yes - additional comparator routinely commissioned</u>** If yes, There are currently three treatment options for patients with residual and recurrent pituitary adenomas: *Source: Policy working group/Policy proposition*
A5.2 What percentage of the total eligible population is estimated to: a) Be clinically assessed for treatment b) Be considered to meet an exclusion criteria following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment?	Total estimated eligible. See above. a) 100% b) 100% c) 100% d) 100% e) 100% *Source: Policy working group*

A6 New Patient Pathway	
A6.1 What percentage of the total eligible population is expected to: a) Be clinically assessed for treatment b) Be considered to meet an exclusion criteria following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment?	a) 100% b) 100% c) 100% d) 100% e) 100% The total eligible patient population has been estimated has been based on a Needs Assessment carried out in 2015/16 in line with the SRS/SRT national procurement. For modelling purposes it has been assumed that all patients will commence treatment. *Source: Policy working group*
A6.2 Specify the nature and duration of the proposed new treatment or intervention.	**Time limited** Stereotactic radiosurgery (SRS) and stereotactic radiotherapy (SRT) is an option for the treatment of residual and recurrent pituitary adenomas following primary treatment with surgery and for those patients that are not able to have surgery as a primary treatment. SRS treatment is delivered in a single fraction and SRT must be delivered in two to five fractions. SRT is sometimes referred to as 'intracranial hypofractionated SRT'. *Source: Policy proposition*

<table>
<tr><th colspan="2">A7 Treatment Setting</th></tr>
<tr><td>A7.1 How is this treatment delivered to the patient?</td><td><u>Acute Trust: day case</u></td></tr>
<tr><td>A7.2 What is the current number of contracted providers for the eligible population by region?</td><td><table>
<tr><td>NORTH</td><td>5</td></tr>
<tr><td>MIDLANDS & EAST</td><td>3</td></tr>
<tr><td>LONDON</td><td>5</td></tr>
<tr><td>SOUTH</td><td>3</td></tr>
</table></td></tr>
<tr><td>A7.3 Does the proposition require a change of delivery setting or capacity requirements?</td><td><u>No</u></td></tr>
<tr><th colspan="2">A8 Coding</th></tr>
<tr><td>A8.1 Specify the datasets used to record the new patient pathway activity.

*expected to be populated for all commissioned activity</td><td>Select all that apply:<table>
<tr><td>Aggregate Contract Monitoring *</td><td>☒</td></tr>
</table></td></tr>
</table>

	Patient level contract monitoring ☐ Patient level drugs dataset ☐ Patient level devices dataset ☐ Devices supply chain reconciliation dataset ☐ Secondary Usage Service (SUS+) ☐ Mental Health Services DataSet (MHSDS) ☐ National Return** ☐ Clinical Database** ☐ Other** ☐
A8.2 Specify how the activity related to the new patient pathway will be identified.	*Select all that apply:* OPCS v4.8 ☐ ICD10 ☐ Treatment function code ☐ Main Speciality code ☐ HRG ☒ SNOMED ☐

	Clinical coding / terming methodology used by clinical profession ☐ SRS/T activity is covered by separate bespoke contracts Describe a suitable Identification Rule for the service or procedure:NCBPS01S Stereotactic Radiosurgery
A8.3 Does the service require the creation of a new specialised service line?	**No**
A9 Monitoring	
A9.1 **Contracts** Specify any new or revised data flow or data collection requirements, needed for inclusion in the NHS Standard Contract Information Schedule.	**None**
A9.2 **Excluded Drugs** For treatments which are tariff excluded drugs, specify the pharmacy monitoring required, for example reporting or use of prior approval systems.	Not applicable.

A9.3 **Business intelligence** Specify analytical information, monitoring and reporting requirements, including validation requirements, to ensure activity is not double charged through existing routes.	All SRS/T activity is funded via separate bespoke contracts following a procurement exercise in 2015/16.
A9.4 **Contract monitoring** Specify contract monitoring to be undertaken by supplier managers, and any changes from current arrangements.	No Changes to current arrangements
A9.5 **Dashboard reporting** Specify whether a dashboard exists for the proposed intervention?	**No**
A9.6 **NICE reporting** Are there any directly applicable NICE or equivalent quality standards which need to be monitored in association with the new policy?	**No**
Section B - Service Impact	
B1 Service Organisation	
B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc)	There are currently 16 contracted SRS/SRT providers
B1.2 Will the proposition change the way the commissioned service is organised?	**No**

<table>
<tr><td>B1.3 Will the proposition require a new approach to the organisation of care?</td><td><u>No</u></td></tr>
<tr><td colspan="2">B2 Geography & Access</td></tr>
<tr><td>B2.1 Where do current referrals come from?</td><td>Select all that apply:<table><tr><td>GP</td><td>☐</td></tr><tr><td>Secondary care</td><td>☐</td></tr><tr><td>Tertiary care</td><td>☒</td></tr><tr><td>Other</td><td>☐</td></tr></table></td></tr>
<tr><td>B2.2 What impact will the new policy have on the sources of referral?</td><td><u>No impact</u></td></tr>
<tr><td>B2.3 Is the new policy likely to improve equity of access?</td><td><u>Increase</u>

Increase expected as a result of better defined access criteria.

Source: Equalities Impact Assessment</td></tr>
<tr><td>B2.4 Is the new policy likely to improve equality of access and/or</td><td><u>No impact</u></td></tr>
</table>

outcomes?	*Source: Equalities Impact Assessment*
B3 Implementation	
B3.1 Will commissioning or provider action be required before implementation of the proposition can occur?	**No action required**
B3.2 **Time to implementation:** Is a lead-in time required prior to implementation?	**No - go to B3.4**
B3.3 **Time to implementation:** If lead-in time is required prior to implementation, will an interim plan for implementation be required?	**Not applicable.**
B3.4 Is a change in provider physical infrastructure required?	**No**
B3.5 Is a change in provider staffing required?	**No**
B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?	**No**
B3.7 Are there changes in the support services that need to be in place?	**No**

<table>
<tr><td>B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)</td><td><u>No</u></td></tr>
<tr><td>B3.9 Is there likely to be either an increase or decrease in the number of commissioned providers? If yes, specify the current and estimated number of providers required in each region</td><td><u>No change</u></td></tr>
<tr><td>B3.10 Specify how revised provision will be secured by NHS England as the responsible commissioner.</td><td>Select all that apply:<table>
<tr><td>Publication and notification of new policy</td><td>☒</td></tr>
<tr><td>Market intervention required</td><td>☐</td></tr>
<tr><td>Competitive selection process to secure increase or decrease provider configuration</td><td>☐</td></tr>
<tr><td>Price-based selection process to maximise cost effectiveness</td><td>☐</td></tr>
<tr><td>Any qualified provider</td><td>☐</td></tr>
<tr><td>National Commercial Agreements e.g. drugs, devices</td><td>☐</td></tr>
<tr><td>Procurement</td><td>☐</td></tr>
<tr><td>Other</td><td>☐</td></tr>
</table></td></tr>
</table>

<table>
<tr><td colspan="2">B4 Place-based Commissioning</td></tr>
<tr><td>B4.1 Is this service currently subject to, or planned for, place-based commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements, STPs)</td><td><u>No</u></td></tr>
<tr><td colspan="2">Section C - Finance Impact</td></tr>
<tr><td colspan="2">C1 Tariff/Pricing</td></tr>
<tr><td>C1.1 Is this treatment paid under national prices?</td><td><u>No</u></td></tr>
<tr><td>C1.2 Is this treatment excluded from national prices?</td><td><u>Yes</u></td></tr>
<tr><td>C1.3 Is this covered under a local price arrangement?

NB: Local pricing may be subject to commercial confidentiality and must not be disclosed.</td><td><u>Yes</u>

If yes, state (2017/18 prices):<table><tr><td>Range</td><td>£3,295 - £7,283</td></tr><tr><td>average</td><td>£5,260</td></tr><tr><td>Certainty</td><td><u>High</u></td></tr></table></td></tr>
<tr><td>C1.4 Is a new price proposed?</td><td><u>No</u></td></tr>
</table>

<table>
<tr><td>C1.5 If VAT is payable, is it included in the proposed price?</td><td><u>Not payable</u></td></tr>
<tr><td>C1.6 Will a prior approval mechanism be used to support implementation of the new policy that will require provider compliance to secure reimbursement?</td><td><u>No</u>

Existing SRS SRT contracts are in place with the nominated providers</td></tr>
<tr><td colspan="2">C2 Average Cost per Patient</td></tr>
<tr><td>C2.1 What is the estimated cost per patient to NHS England, in years 1-5, including follow-up where required?</td><td><table><tr><td>YR1</td><td>£5,153</td></tr><tr><td>YR2</td><td>£5,062</td></tr><tr><td>YR3</td><td>£5,029</td></tr><tr><td>YR4</td><td>£5,031</td></tr><tr><td>YR5</td><td>£5,024</td></tr></table></td></tr>
<tr><td colspan="2">C3 Overall Cost Impact of this Policy to NHS England</td></tr>
<tr><td>C3.1 Specify the budget impact of the proposal on NHS England.</td><td><u>Cost saving</u>

The change of treatment modalities to SRS SRT and away from conventional radiotherapy, surgical interventions and other medical treatments will reduce</td></tr>
</table>

	cost over the period analysed. However, it should be noted that whilst the impact assessment is demonstrating a significant saving moving from £324.5k in year 1 to £1.2m in year 5, this is in line with the assumptions used for the SRS/T recent national procurement. It is important that the savings are not double counted by commissioners, who will already have taken these into account when establishing the new SRS/T contracts.
C3.2 If the budget impact on NHS England cannot be identified set out the reasons why this cannot be measured.	Not applicable.
C3.3 If the activity is subject to a change of commissioning responsibility, from CCG to NHS England, has a methodology for the transfer of funds been agreed, and calculated?	Not applicable.
C3.4 If the activity is subject to a change of commissioning responsibility, from CCG to NHS England, are CCGs aware of the values to be transferred?	Not applicable.
C4 Overall cost impact of this policy to the NHS as a whole	
C4.1 Specify the budget impact of the proposal on other parts of the NHS.	Budget impact for CCGs: **Cost neutral**

	Budget impact for providers: **Cost neutral**
C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	**Cost saving** The change of treatment modalities to SRS SRT and away from conventional radiotherapy, surgical interventions and other medical treatments will reduce cost over the period analysed. However, it should be noted that whilst the impact assessment is demonstrating a significant saving moving from £324.5k in year 1 to £1.2m in year 5, this is in line with the assumptions used for the SRS/T recent national procurement. It is important that the savings are not double counted by commissioners, who will already have taken these into account when establishing the new SRS/T contracts.
C4.3 Where the budget impact is unknown set out the reasons why this cannot be measured	Not applicable.
C4.4 Are there likely to be any costs or savings for non-NHS commissioners and/or public sector funders?	**No**
C5 Funding	

C5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified, e.g. decommissioning less clinically or cost-effective services.	Not applicable – this policy is cost saving.
C6 Financial Risks Associated with Implementing this Policy	
C6.1 What are the material financial risks to implementing this policy?	None identified
C6.2 How can these risks be mitigated?	Not applicable.
C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	Assumed that the number of SRS/T treatments will increase from a baseline of 132 in 2017/18 to 400 over a 3 year period. Actual numbers will depend on patient treatment pathways. As this is cost saving overall, only the most likely numbers have been modelled.
C6.4 What scenario has been approved and why?	As this policy is cost saving overall, only the most likely numbers have been modelled.
C7 Value for Money	
C7.1 What evidence is available that the treatment is cost effective?	**Modelling indicates likely to be cost effective compared to existing and/or alternative**

<table>
<tr><td>C7.2 What issues or risks are associated with this assessment? e.g. quality or availability of evidence</td><td>Select all that apply:<table><tr><td>Some uncertainty about number of eligible patients</td><td>☒</td></tr><tr><td>Some uncertainty about estimates of uptake</td><td>☐</td></tr><tr><td>Some uncertainty about future drug prices</td><td>☐</td></tr><tr><td>Potential for legal challenge</td><td>☐</td></tr></table></td></tr>
<tr><td colspan="2">C8 Cost Profile</td></tr>
<tr><td>C8.1 Are there non-recurrent capital or revenue costs associated with this policy?</td><td><u>No</u></td></tr>
<tr><td>C8.2 If yes, confirm the source of funds to meet these costs.</td><td>Not applicable.</td></tr>
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