

Integrated Impact Assessment Report for Clinical Commissioning Policies

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|---|--|------------------------|-----------|
| Service Specification Reference Number | 1868 | | |
| Service Specification Title | Stroke Thrombectomy Services for Acute Ischaemic Stroke Proposal <u>for routine commission</u> (ref A3.1) | | |
| Lead Commissioner | Jacque Kemp | Clinical Leads | Tony Rudd |
| Finance Lead | Justine Stalker Booth | Analytical Lead | |

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About this Impact Assessment: instructions for completion and explanatory notes

- Each section is divided into themes.
- Each theme sets out a number of questions.
- All questions are answered by selecting a drop down option or including free text.
- Free text boxes are provided to enable succinct relevant commentary to be added which explains the rationale for response or assumption. Please limit responses to 3 sentences of explanatory text.
- Data in this document is either drawn from one of the relevant Service Specification 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 approximately 80,000 stroke admissions in England per year. Currently, around 12% of all stroke patients receive intravenous thrombolysis and the majority of patients suitable for thrombectomy will come from this group.

*Source: Service Specification section 6
Clinical Evidence Review*

A1.2 Number of patients currently eligible for the treatment according to the proposed Service Specification commissioning criteria.

It is anticipated that 8,000 people per year would fulfil the criteria for consideration for thrombectomy.

A1.3 Age group for which the treatment is proposed according to the Service Specification commissioning criteria.

All ages

[Click here to enter text.](#)

A1.4 Age distribution of the patient population eligible according to the proposed Service Specification commissioning criteria

Source: Clinical Evidence Review, Service Specification

The risk of having a stroke doubles every decade after the age of 55. By the age of 75, 1 in 5 women and 1 in 6 men will have a stroke. 1 in 4 (26%) of strokes in the UK occur in people under 65 years old.

A1.5 How is the population currently distributed geographically?

Evenly

If unevenly, estimate regional distribution by %:

| | |
|-----------------|---------|
| North | enter % |
| Midlands & East | enter % |

| | | | |
|---|--------|---------|--|
| | London | enter % | |
| | South | enter % | |
| <p><i>Source: Service Specification section 6, Evidence Review</i></p> <p>There is no known evidence of differences in geographical distribution in England for people suffering from stroke.</p> | | | |

A2 Future Patient Population & Demography

| | |
|---|---|
| <p>A2.1 Projected changes in the disease/condition epidemiology, such as incidence or prevalence (prior to applying the new Service Specification) in 2, 5, and 10 years?</p> | <p><u>Constant</u></p> <p>There is no anticipated growth in the numbers of people suffering a stroke as although the incidence is dropping the population is ageing.</p> <p>Ageing population as the incidence of stroke increases with age. However due to improved prevention the incidence in <75 has been decreasing.</p> <p>A phased implementation commissioning plan is proposed to allow for development of services and specialists.</p> <p><i>Source: Clinical Evidence Review, Service Specification Working Group</i></p> |
|---|---|

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|--|---|
| <p>A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?</p> | <p>No</p> <p><i>Source: Clinical Evidence Review, Service Specification Working Group</i></p> |
|--|---|

| | | | | |
|---|--|---------|-------|--|
| <p>A2.3 Expected net increase or decrease in the number of patients who will be eligible for the service, according to the proposed service specification commissioning criteria, per year in years 2-5 and 10?</p> | <table border="1"> <tr> <td>YR2 +/-</td> <td>2,500</td> </tr> </table> | YR2 +/- | 2,500 | |
| | YR2 +/- | 2,500 | | |
| | <table border="1"> <tr> <td>YR3 +/-</td> <td>3,250</td> </tr> </table> | YR3 +/- | 3,250 | |
| | YR3 +/- | 3,250 | | |
| <table border="1"> <tr> <td>YR4 +/-</td> <td>4,000</td> </tr> </table> | YR4 +/- | 4,000 | | |
| YR4 +/- | 4,000 | | | |
| <table border="1"> <tr> <td>YR5 +/-</td> <td>6,000</td> </tr> </table> | YR5 +/- | 6,000 | | |
| YR5 +/- | 6,000 | | | |

| | | | | |
|--|--|----------|-------|---|
| <p>Are these numbers in line with ONS growth assumptions for the age specific population? If not please justify the growth assumptions made.</p> | <table border="1"> <tr> <td data-bbox="1077 102 1341 148">YR10 +/-</td> <td data-bbox="1341 102 1592 148">9,428</td> </tr> </table> | YR10 +/- | 9,428 | <p>Due to the need to set up services to meet the expected number of treatments with thrombectomy, this will range from around 1,000 in year 1; increasing to 4,000 in year 5 with a rapid increase of access following over the next 2-3 years up to the total estimated of 8,000 patients.</p> <p><i>Source: Service specification section 3.1</i></p> <p><u>Yes</u></p> |
| YR10 +/- | 9,428 | | | |
| <p>A3 Activity</p> | | | | |
| <p>A3.1 What is the purpose of new Service Specification?</p> | <p><u>Confirm routine commissioning position of an additional new treatment</u></p> <p>This Service Specification extends access to a treatment to the pathway for a group of patients who have suffered acute ischaemic stroke and fulfil the criteria and are geographically placed that means they cannot access thrombectomy services within a neuroscience centre within the recommended timeframe for best outcomes.</p> | | | |
| <p>A3.2 What is the annual activity associated with the existing pathway for the eligible population?</p> | <p>80,000 admissions per year for stroke with 8,000 of these being eligible for treatment. These patients currently only receive thrombolysis and rehab and nursing care.</p> <p>The current service configuration will need development to meet the projection of 8,000 per annum mentioned above. The estimates of activity for year 1 to 5 (see below) represent a stepped increase running alongside the service development during this period.</p> | | | |

| | |
|--|---|
| | <p>For the 5 year period from 18/19 to 22/23 the activity is shown below:</p> <ul style="list-style-type: none"> - Year 1: 1,750 - Year 2: 2,500 - Year 3: 3,250 - Year 4: 4,000 - Year 5: 6,000 <p>By year 6 up to a total anticipated of 8,000</p> <p><i>Source: Clinical Evidence Review, Service Specification Working Group</i></p> |
| <p>A3.3 What is the estimated annual activity associated with the proposed Service Specification pathway for the eligible population?</p> | <p>For 2017/18 nearly 900 thrombectomies were performed. During 2018/19 1,200 thrombectomies were performed 2019/20 estimated 2,000 thrombectomies</p> <p><i>Source: Service Specification Working Group</i> Please specify</p> |
| <p>A3.4 What is the estimated annual activity associated with the next best alternative comparator pathway for the eligible population? If the only alternative is the existing pathway, please state 'not applicable' and move to A4.</p> | <p>There is no other treatment option for this group of patients other than rehabilitation for disability and good nursing care.</p> <p><i>Source: Service Specification Working Group</i></p> |
| <p>A4 Existing Patient Pathway</p> | |

| | |
|---|---|
| <p>A4.1 Existing pathway: Describe the relevant currently routinely commissioned:</p> <ul style="list-style-type: none"> • Treatment or intervention • Patient pathway • Eligibility and/or uptake estimates. | <p>No other pathway beyond thrombolysis</p> |
| <p>A4.2. What are the current treatment access and stopping criteria?</p> | <p>If eligibility criteria are fulfilled then it would be on a rare occasion that a patient would not proceed to treatment.</p> <p><i>Source: Service Specification , Service Specification Working Group</i></p> |
| <p>A4.3 What percentage of the total eligible population is expected to:</p> <ol style="list-style-type: none"> Be clinically assessed for treatment Be considered to meet an exclusion criteria following assessment Choose to initiate treatment Comply with treatment Complete treatment? | <p>If not known, please specify</p> <ol style="list-style-type: none"> 100% 0% 100% 100% 100% <p><i>Source: Service Specification Working Group</i></p> |
| <p>A5 Comparator (next best alternative treatment) Patient Pathway (NB: comparator/next best alternative does not refer to current pathway but to an alternative option)</p> | |
| <p>A5.1 Next best comparator: Is there another ‘next best’ alternative treatment which is a relevant comparator? <i>If yes, describe relevant</i></p> <ul style="list-style-type: none"> • <i>Treatment or intervention</i> • <i>Patient pathway</i> | <p><u>No</u></p> <p>If yes, Click here to enter text.</p> <p><i>Source: Service Specification Working Group</i></p> |

| | |
|---|--|
| <ul style="list-style-type: none"> • <i>Actual or estimated eligibility and uptake</i> | |
| <p>A5.2 What percentage of the total eligible population is estimated to:</p> <ul style="list-style-type: none"> 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? | <p>Not applicable</p> <ul style="list-style-type: none"> a) 100% b) 0% c) 100% d) 100% e) 10% <p><i>Source: Service Specification working group</i></p> |
| <p>A6 New Patient Pathway</p> | |
| <p>A6.1 What percentage of the total eligible population is expected to:</p> <ul style="list-style-type: none"> 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? | <p>If not known, please specify</p> <ul style="list-style-type: none"> a) 100% b) 0% c) 100% d) 100% e) 100% <p><i>Source: Service Specification Working Group</i></p> |
| <p>A6.2 Specify the nature and duration of the proposed new treatment or intervention.</p> | <p><u>Time limited</u></p> <ol style="list-style-type: none"> 1. CT scan confirms likely ischaemic stroke 2. CTA confirms due to large artery occlusion (40%) 3. Confirm within 4.5 hours of stroke onset <ul style="list-style-type: none"> • If yes, start IV thrombolysis if appropriate whilst reconstruct Computed tomography angiography (CTA) images for review 4. Moderate to severe stroke (<i>on NIHSS assessment tool</i>) |

5. Assess for “no clinical or CT scan exclusions to thrombectomy”
(*estimated pre stroke Rankin & ASPECTS on CT & vascular access issues*)
6. If yes to all above then eligible for thrombectomy

Only around 40% of stroke admissions will have a proximal large artery occlusion (LAO) as the cause (of the stroke). Only this group can be treated by thrombectomy. In total per annum in England this number is ~29, 0000. (Derived from PEARS modelling work presented at UK Stroke Forum Nov 2016) CT Angiography is required to confirm whether LAO is present or not.

Of that group with LAO stroke, the current evidence base does not apply to a reasonable proportion (very mild strokes or people with major pre-existing disability were not included in the trials of thrombectomy) and trial evidence suggests that if there are extensive changes of brain damage already present on CT scan at the time of presentation that thrombectomy is unlikely to be beneficial.

Like IV thrombolysis the benefits of thrombectomy are very time dependent & concentrated in those who can be treated within 6 hours of stroke onset – in practice that means arriving at hospital within 4.5h in order to achieve thrombectomy by 6 hours. SSNAP data indicate that $\frac{3}{4}$ of Large Artery Occlusion (LAO) stroke patients present within 4.5h of onset.

Applying all these exclusions reduces the number eligible for thrombectomy down to just under 8,000 (or 10% of all stroke admissions).

Source: Service Specification , Service Specification Working Group

A7 Treatment Setting

A7.1 How is this treatment delivered to the patient?

Select all that apply:

| | |
|------------------------------------|-------------------------------------|
| Emergency/Urgent care attendance | <input type="checkbox"/> |
| Acute Trust: inpatient | <input checked="" type="checkbox"/> |
| Acute Trust: day patient | <input type="checkbox"/> |
| Acute Trust: outpatient | <input type="checkbox"/> |
| Mental Health provider: inpatient | <input type="checkbox"/> |
| Mental Health provider: outpatient | <input type="checkbox"/> |
| Community setting | <input type="checkbox"/> |
| Homecare | <input type="checkbox"/> |
| Other | <input type="checkbox"/> |

Please specify:

Neuroscience centre.

There may be some areas where due to geographical access and transfer times, thrombectomy services may not be delivered within a neuroscience centre but must conform to the service specification standards

A7.2 What is the current number of contracted providers for the eligible population by region?

| | Neuroscience Centres |
|-----------------|----------------------|
| NORTH | 8 |
| MIDLANDS & EAST | 5 |
| LONDON | 6 |

| | | |
|--|-------|---|
| | SOUTH | 5 |
|--|-------|---|

A7.3 Does the requires a change of delivery setting or capacity requirements?

Yes
 Yes development of services is part of the phased commissioning plan
Source: Service Specification Working Group

A8 Coding

A8.1 Specify the datasets used to record the new patient pathway activity.

*expected to be populated for all commissioned activity

Select all that apply:

| | |
|---|-------------------------------------|
| Aggregate Contract Monitoring * | <input checked="" type="checkbox"/> |
| Patient level contract monitoring | <input checked="" type="checkbox"/> |
| Patient level drugs dataset | <input type="checkbox"/> |
| Patient level devices dataset | <input type="checkbox"/> |
| Devices supply chain reconciliation dataset | <input type="checkbox"/> |
| Secondary Usage Service (SUS+) | <input checked="" type="checkbox"/> |
| Mental Health Services DataSet (MHSDS) | <input type="checkbox"/> |
| National Return** | <input type="checkbox"/> |
| Clinical Database** | <input type="checkbox"/> |
| Other** | <input type="checkbox"/> |

**If National Return, Clinical database or other selected, please specify:

A8.2 Specify how the activity related to the new patient pathway will be identified.

Select all that apply:

| | |
|---|-------------------------------------|
| OPCS v4.8 | <input checked="" type="checkbox"/> |
| ICD10 | <input checked="" type="checkbox"/> |
| Treatment function code | <input checked="" type="checkbox"/> |
| Main Speciality code | <input checked="" type="checkbox"/> |
| HRG | <input checked="" type="checkbox"/> |
| SNOMED | <input type="checkbox"/> |
| Clinical coding / terming methodology used by clinical profession | <input type="checkbox"/> |

As per Health and Social care Information Centre (HSCIC) – Clinical Classifications Service issued on the 26 November 2016, the OPCS-4 codes for Mechanical clot retrieval for treating acute ischaemic stroke are:

1. L71.2 Percutaneous transluminal embolectomy of artery

Includes: Percutaneous transluminal thrombectomy of artery:

- Y53.- Approach to organ under image control
- Z35. Cerebral artery or O28.1 Basilar artery

2. ICD-10 of I63.9 Cerebral infarction, unspecified (in conjunction with the codes above this will identify thrombectomy activity).

A8.3 Identification Rules for Drugs:
How are drug costs captured?

Not applicable

| | |
|--|---|
| <p>A8.4 Identification Rules for Devices: How are device costs captured?</p> | <p><u>Not excluded from Tariff and covered within existing National or Local prices</u></p> <p>If the device is covered by an existing category of HCTED please specify the Device Category (as per the National Tariff Payment System Guidance).</p> <p>If the device is not excluded from tariff nor covered within existing national or local prices please specify details of action required and confirm that this has been discussed with the HCTED team.</p> |
| <p>A8.5 Identification Rules for Activity: How are activity costs captured?</p> | <p><u>Already correctly captured by an existing specialised service line (NCBPS code within the PSS Tool)</u></p> <p>If activity costs are already captured please specify the specialised service code and description (e.g. NCBPS01C Chemotherapy).</p> <p>The appropriate codes are : NCPBS08O – Neurology</p> |
| <p>A9 Monitoring</p> | |
| <p>A9.1 Contracts Specify any new or revised data flow or data collection requirements, needed for inclusion in the NHS Standard Contract Information Schedule.</p> | <p><u>Yes - other</u> Please specify: Schedule 6 to be amended Click here to enter text.</p> |
| <p>A9.2 Excluded Drugs and Devices (not covered by the Zero Cost Model)</p> | <p><i>Select all that apply:</i> _____</p> |

| | | | | | | | |
|--|--|---------------------|--------------------------|---------|--------------------------|----------------------|--------------------------|
| <p>For treatments which are tariff excluded drugs or devices not covered by the Zero Cost Model, specify the pharmacy or device monitoring required, for example reporting or use of prior approval systems.</p> | <table border="1"> <tr> <td data-bbox="1086 97 1509 156">Drugs or Device MDS</td> <td data-bbox="1516 97 1590 156"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1086 156 1509 215">Blueteq</td> <td data-bbox="1516 156 1590 215"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1086 215 1509 277">Other prior approval</td> <td data-bbox="1516 215 1590 277"><input type="checkbox"/></td> </tr> </table> | Drugs or Device MDS | <input type="checkbox"/> | Blueteq | <input type="checkbox"/> | Other prior approval | <input type="checkbox"/> |
| Drugs or Device MDS | <input type="checkbox"/> | | | | | | |
| Blueteq | <input type="checkbox"/> | | | | | | |
| Other prior approval | <input type="checkbox"/> | | | | | | |
| <p>A9.3 Business intelligence Is there potential for duplicate reporting?</p> | <p><u>No</u> If yes, please specify mitigation: Click here to enter text.</p> | | | | | | |
| <p>A9.4 Contract monitoring Is this part of routine contract monitoring?</p> | <p><u>Yes</u> Reporting of activity via SUS with activity and outcomes via SSNAP and QST portal.</p> | | | | | | |
| <p>A9.5 Dashboard reporting Specify whether a dashboard exists for the proposed intervention?</p> | <p><u>Yes</u> 4 monthly outcome reporting (so that it aligns with current audit reporting from SSNAP) Compliance with specification and implementation plan if required. Click here to enter text.</p> | | | | | | |
| <p>A9.6 NICE reporting Are there any directly applicable NICE or equivalent quality standards which need to be monitored in association with the new Service Specification?</p> | <p><u>No</u></p> | | | | | | |
| <p>Section B - Service Impact</p> | | | | | | | |
| | | | | | | | |

| B1 Service Organisation | | | | | | | | | |
|---|--|----|--------------------------|----------------|-------------------------------------|---------------|-------------------------------------|-------|--------------------------|
| B1.1 Describe how the service is currently organised? (I.e. tertiary centres, networked provision etc.) | Stroke care is organised within provider networks, this intervention will require referral to an approved and commissioned Thrombectomy centre with an SLA with a recognised networked Neuroscience centre. <i>Source: Service Specification</i> | | | | | | | | |
| B1.2 Will the specification change the way the commissioned service is organised? | Yes Potential for Clinical Commissioning Groups (CCGs) to unbundle the stroke pathway payment when reduction in length of stay is understood. <i>Source: Service Specification Working Group</i> | | | | | | | | |
| B1.3 Will the specification require a new approach to the organisation of care? | Some areas may need to network to achieve optimal access over a 24/7 period whilst services develop. | | | | | | | | |
| B2 Geography & Access | | | | | | | | | |
| B2.1 Where do current referrals come from? | <p><i>Select all that apply:</i></p> <table border="1" data-bbox="1088 1023 1599 1262"> <tbody> <tr> <td data-bbox="1088 1023 1512 1082">GP</td> <td data-bbox="1512 1023 1599 1082"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1088 1082 1512 1141">Secondary care</td> <td data-bbox="1512 1082 1599 1141"><input checked="" type="checkbox"/></td> </tr> <tr> <td data-bbox="1088 1141 1512 1200">Tertiary care</td> <td data-bbox="1512 1141 1599 1200"><input checked="" type="checkbox"/></td> </tr> <tr> <td data-bbox="1088 1200 1512 1262">Other</td> <td data-bbox="1512 1200 1599 1262"><input type="checkbox"/></td> </tr> </tbody> </table> <p>Emergency departments and stroke services. Hospitals with hyper acute stroke units (HASU)</p> | GP | <input type="checkbox"/> | Secondary care | <input checked="" type="checkbox"/> | Tertiary care | <input checked="" type="checkbox"/> | Other | <input type="checkbox"/> |
| GP | <input type="checkbox"/> | | | | | | | | |
| Secondary care | <input checked="" type="checkbox"/> | | | | | | | | |
| Tertiary care | <input checked="" type="checkbox"/> | | | | | | | | |
| Other | <input type="checkbox"/> | | | | | | | | |

| | |
|---|--|
| <p>B2.2 What impact will the new Service Specification have on the sources of referral?</p> | <p><u>Increase</u> Patients who are admitted to a hospital Hyper Acute Stroke Unit (HASU) where it is not co located with a thrombectomy centre will require a critical transfer to a Thrombectomy centre.</p> |
| <p>B2.3 Is the new Service Specification likely to improve equity of access?</p> | <p><u>Increase</u> Please specify: Yes by increasing the availability of the provision of the service. <i>Source: Equalities Impact Assessment</i></p> |
| <p>B2.4 Is the new Service Specification likely to improve equality of access and/or outcomes?</p> | <p><u>Increase</u> Please specify: Yes as above in B2.3 <i>Source: Equalities Impact Assessment</i></p> |
| <p>B3 Implementation</p> | |
| <p>B3.1 Will commissioning or provider action be required before implementation of the specification can occur?</p> | <p><u>Service organisation action</u> Please specify: Phased implementation proposed within commissioning implementation plan</p> |
| <p>B3.2 Time to implementation: Is a lead-in time required prior to implementation?</p> | <p><u>Yes - go to B3.3</u> If yes, specify the likely time to implementation: Phased implementation proposed within commissioning implementation plan</p> |

| | |
|--|---|
| <p>B3.3 Time to implementation: If lead-in time is required prior to implementation, will an interim plan for implementation be required?</p> | <p><u>Yes</u> If yes, outline the plan: Click here to enter text.</p> |
| <p>B3.4 Is a change in provider physical infrastructure required?</p> | <p><u>Yes</u> Potential need for further access to services for thrombectomy when the neuroscience centres consider transfer times.</p> |
| <p>B3.5 Is a change in provider staffing required?</p> | <p><u>Yes</u> See above Increase in number of interventional neuroradiologists or equivalent role to deliver thrombectomy 24/7 and acute aneurysm coiling 7/7.</p> |
| <p>B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?</p> | <p><u>Yes</u> Please specify: Full immediate access to imaging, critical care and anaesthetics as detailed in the service specification. Approximately $\frac{3}{4}$ of patients will require an additional ambulance transfer therefore access to critical (critical response times) ambulance transfer.</p> |
| <p>B3.7 Are there changes in the support services that need to be in place?</p> | <p><u>Yes</u> Please specify: CT Angiography needs to be available for stroke patients in any hospital admitting/managing acute stroke. Acute stroke care unit and HASU and access to patient transport for repatriation.</p> |
| <p>B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)</p> | <p><u>No</u> Please specify:</p> |

Operational Delivery Network (ODN) framework already in place for Stroke services

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

Increase

Please complete table: Not applicable

| Region | Current no. of providers | Future State expected range | Provisional or confirmed |
|-----------------|--------------------------|-----------------------------|--------------------------|
| North | 8 | 8 | <u>C</u> |
| Midlands & East | 5 | 6-7 | <u>P</u> |
| London | 6 | 4-5 | <u>P</u> |
| South | 5 | 5 | <u>C</u> |
| Total | 24 | 24-26 | <u>P</u> |

Please specify:

The increase in centres delivering thrombectomy outside of a neuroscience centre will be phased to ensure that centres are equitably placed for urgent access and sustainable with appropriate throughput. It is estimated that there is a requirement for 3-5 of these centres nationally

B3.10 Specify how revised provision will be secured by NHS England as the responsible commissioner.

Select all that apply:

| | |
|---|-------------------------------------|
| Publication and notification of new Service Specification | <input checked="" type="checkbox"/> |
| Market intervention required | <input type="checkbox"/> |
| Competitive selection process to secure increase or decrease provider configuration | <input type="checkbox"/> |

| | | |
|--|--|-------------------------------------|
| | Price-based selection process to maximise cost effectiveness | <input type="checkbox"/> |
| | Any qualified provider | <input checked="" type="checkbox"/> |
| | National Commercial Agreements e.g. drugs, devices | <input type="checkbox"/> |
| | Procurement | <input type="checkbox"/> |
| | Other | <input type="checkbox"/> |
| Please specify: Click here to enter text. | | |

B4 Place-based Commissioning

| | |
|--|---|
| B4.1 Is this service currently subject to, or planned for, place-based commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements, STPs) | No Please specify: Click here to enter text. |
|--|---|

Section C - Finance Impact

C1 Tariff/Pricing

| | | |
|--|-------------------------------|---|
| C1.1 How is the service contracted and/or charged? Only specify for the relevant section of the patient pathway | <i>Select all that apply:</i> | |
| | Drugs | Not separately charged – part of local or national tariffs <input type="checkbox"/> |
| | | Excluded from tariff – pass through <input checked="" type="checkbox"/> |
| | | Excluded from tariff - other <input type="checkbox"/> |

| | | | |
|--|--|--|-------------------------------------|
| | Devices | Not separately charged – part of local or national tariffs | <input type="checkbox"/> |
| | | Excluded from tariff (excluding ZCM) – pass through | <input type="checkbox"/> |
| | | Excluded from tariff (excluding ZCM) – other | <input type="checkbox"/> |
| | | Via Zero Cost Model | <input type="checkbox"/> |
| | Activity | Paid entirely by National Tariffs | <input type="checkbox"/> |
| | | Paid entirely by Local Tariffs | <input type="checkbox"/> |
| | | Partially paid by National Tariffs | <input checked="" type="checkbox"/> |
| | | Partially paid by Local Tariffs | <input type="checkbox"/> |
| | | Part/fully paid under a Block arrangement | <input type="checkbox"/> |
| | | Part/fully paid under Pass-Through arrangements | <input type="checkbox"/> |
| | | Part/fully paid under Other arrangements | <input type="checkbox"/> |
| | <p>The revenue cost per patient is based on HRG YA13Z.</p> <p>As per HSCIC – Clinical Classifications Service issued on the 26 November 2016, the OPCS-4 codes for Mechanical clot retrieval for treating acute ischaemic stroke are:</p> <p>1. L71.2 Percutaneous transluminal embolectomy of artery</p> <p>Includes: Percutaneous transluminal thrombectomy of artery:</p> <ul style="list-style-type: none"> • Y53.- Approach to organ under image control • Z35. Cerebral artery or O28.1 Basilar artery | | |

| | |
|---|--|
| | 2. ICD-10 of I63.9 Cerebral infarction, unspecified (in conjunction with the codes above this will identify Thrombectomy activity). |
| <p>C1.2 Drug Costs</p> <p>Where not included in national or local tariffs, list each drug or combination, dosage, quantity, list price including VAT if applicable and any other key information e.g. Chemotherapy Regime.</p> <p>NB discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.</p> | Not applicable |
| <p>C1.3 Device Costs</p> <p>Where not included in national or local tariff, list each element of the excluded device, quantity, list or expected price including VAT if applicable and any other key information.</p> <p>NB: Discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.</p> | Not applicable |
| <p>C1.4 Activity Costs covered by National Tariffs</p> <p>List all the HRG codes, HRG descriptions, national tariffs (excluding MFF), volume and other key costs (e.g. specialist top up %)</p> | <p>Click here to enter text.</p> <p>Thrombectomy Pathway:</p> <p>A patient would have:</p> <ol style="list-style-type: none"> 1. Both the specialty code and treatment function code should be reported as 400 for Neurology. This is to ensure that the activity does not default to CCGs and the specialised top up is applied consistently across all providers 2. The revenue cost per patient is based on HRG YA13Z. The cost of the device is included in the tariff. (As detailed in the NICE IPC548 |

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| | <p>which describes the appropriate coding of mechanical clot retrieval.)</p> <ol style="list-style-type: none"> 3. As per HSCIC – Clinical Classifications Service issued on the 26 November 2016, the OPCS-4 codes for Mechanical clot retrieval for treating acute ischaemic stroke are: 4. L71.2 Percutaneous transluminal embolectomy of artery 5. Includes: Percutaneous transluminal thrombectomy of artery: 6. Y53.- Approach to organ under image control 7. Z35. Cerebral artery 8. ICD-10 of I63.9 Cerebral infarction, unspecified (in conjunction with the codes above this will identify Thrombectomy activity). | | |
| <p>C1.5 Activity Costs covered by Local Tariff List all the HRGs (if applicable), HRG or local description, estimated average tariff, volume and any other key costs. Also indicate whether the Local Tariff(s) is/are newly proposed or established and if newly proposed how is has been derived, validated and tested.</p> | Not applicable | | |
| <p>C1.6 Other Activity Costs not covered by National or Local Tariff Include descriptions and estimates of all key costs.</p> | Not applicable | | |
| <p>C1.7 Are there any prior approval mechanisms required either during implementation or permanently?</p> | <p>No Please specify:</p> | | |
| <p>C2 Average Cost per Patient</p> | | | |
| <p>C2.1 What is the estimated cost per patient to NHS England, in years 1-5, including follow-up where required?</p> | <table border="1" style="width: 100%;"> <tr> <td style="width: 30%;">YR1</td> <td style="width: 70%; text-align: center;">£13,885</td> </tr> </table> | YR1 | £13,885 |
| YR1 | £13,885 | | |

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| Are there any changes expected in year 6-10 which would impact the model? | YR2 | £13,885 |
| | YR3 | £13,885 |
| | YR4 | £13,885 |
| | YR5 | £13,885 |
| | If yes, please specify: No | |

C3 Overall Cost Impact of this Service Specification to NHS England

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| C3.1 Specify the budget impact of the proposal on NHS England in relation to the relevant pathway. | <u>Cost neutral</u> Please specify: Costs covered within implementation of the thrombectomy policy |
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| C3.2 If the budget impact on NHS England cannot be identified set out the reasons why this cannot be measured. | Not Applicable |
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| 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 identified, and calculated? | Not applicable |
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C4 Overall cost impact of this Service Specification to the NHS as a whole

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|---|--|
| <p>C4.1 Specify the budget impact of the proposal on other parts of the NHS.</p> | <p>Budget impact for CCGs: <u>Cost neutral</u> Budget impact for providers: <u>No impact on providers</u> Please specify:</p> |
| <p>C4.2 Taking into account responses to C3.1 and C4.1 specify the budget impact to the NHS as a whole.</p> | <p><u>Cost neutral</u> Please specify: Costs associated with thrombectomy policy not service specification. The assumption is cost neutral for the service specification. Year 1: £0.0m Year 2: £0.0m Year 5: £0.0m</p> |
| <p>C4.3 Where the budget impact is unknown set out the reasons why this cannot be measured</p> | <p>Not applicable</p> |
| <p>C4.4 Are there likely to be any costs or savings for non-NHS commissioners and/or public sector funders?</p> | <p><u>Yes</u> Please specify: Yes: It is expected that savings generated would also arise outside the healthcare system through a reduction in rates of disability and dependence in stroke survivors. Poor outcomes after stroke are disproportionately much higher in the stroke patients eligible for thrombectomy</p> |
| <p>C5 Funding</p> | |

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| <p>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.</p> | <p>N/A</p> |
| <p>C6 Financial Risks Associated with Implementing this Service Specification</p> | |
| <p>C6.1 What are the material financial risks to implementing this Service Specification?</p> | <p>There may be risks around the implementation plan (Commissioning) being proposed and how quickly the current services can be mobilised to meet the requirements for a 24/7 service, this is due to the current low numbers of staff to carry out the intervention:</p> <p>A further potential risk is around the level of confidence in the activity assumptions. These are based on assumptions from current clinical practice and therefore may overstate future activity.</p> <p>There are ongoing randomised trials that may extend the evidence base in terms of reducing the proportion of thrombectomy exclusions. For instance:</p> <ul style="list-style-type: none"> • Strokes where time onset is unknown (e.g. wake up strokes) may be proven to benefit from thrombectomy (↑15%) • Thrombectomy for more vessel occlusion sites may become evidence based (↑2-5%) • Thrombectomy may be proven for mild strokes with LAO present (↑15-20%). <p>Together these ongoing trials could increase numbers eligible by ~35%.</p> <p>If these trials are published and change is considered a new proposal will be submitted for consideration for funding.</p> |

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| C6.2 How can these risks be mitigated? | The phased implementation plan as described in C6.1 above is intended to provide this mitigation due to current service configuration and a shortage in trained staff to (i.e. neuro-interventionists). | | | | |
| C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios? | Phased implementation as per the commissioning plan. | | | | |
| C6.4 What scenario has been approved and why? | The mid-point of the expected cohort has been modelled as this is the most likely number of patients each year (excluding backlog). | | | | |
| C7 Value for Money | | | | | |
| C7.1 What published evidence is available that the treatment is cost effective as evidenced in the evidence review? | <p><u>Published evidence indicates the treatment has the potential to be cost-effective</u></p> <p>Please specify:</p> <p>NICE- Mechanical clot retrieval for treating acute ischaemic stroke - Interventional Procedures Guidance [IPG548] Published date: February 2016</p> <p>Sentinel Stroke National Audit Programme</p> <p>Cost and cost-effectiveness analysis 2016</p> | | | | |
| C7.2 Has other data been identified through the service specification development relevant to the assessment of value for money? | <p><i>Select all that apply:</i></p> <table border="1" data-bbox="1088 1174 2130 1358"> <tr> <td data-bbox="1088 1174 2056 1265">Available pricing data suggests the treatment is equivalent cost compared to current/comparator treatment</td> <td data-bbox="2056 1174 2130 1265"><input type="checkbox"/></td> </tr> <tr> <td data-bbox="1088 1265 2056 1358">Available pricing data suggests the treatment is lower cost compared to current/comparator treatment</td> <td data-bbox="2056 1265 2130 1358"><input type="checkbox"/></td> </tr> </table> | Available pricing data suggests the treatment is equivalent cost compared to current/comparator treatment | <input type="checkbox"/> | Available pricing data suggests the treatment is lower cost compared to current/comparator treatment | <input type="checkbox"/> |
| Available pricing data suggests the treatment is equivalent cost compared to current/comparator treatment | <input type="checkbox"/> | | | | |
| Available pricing data suggests the treatment is lower cost compared to current/comparator treatment | <input type="checkbox"/> | | | | |

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| | Available clinical practice data suggests the new treatment has the potential to improve value for money | <input type="checkbox"/> |
| | Other data has been identified | <input type="checkbox"/> |
| | No data has been identified | <input type="checkbox"/> |
| | The data supports a high level of certainty about the impact on value | <input checked="" type="checkbox"/> |
| | The data does not support a high level of certainty about the impact on value | <input type="checkbox"/> |
| | Please specify: Service development required to achieve numbers of specialist staff. | |
| C8 Cost Profile | | |
| C8.1 Are there non-recurrent capital or revenue costs associated with this Service Specification? | <u>Yes</u> If yes, specify type and range: PACS workstations at home for all neurointerventionists on the coiling/thrombectomy rota & with full connectivity to all hospital PACS systems referring into their service (circa £12,000 per interventionist) | |
| C8.2 If yes, confirm the source of funds to meet these costs. | Capital funding to be covered by provider development plans | |