Integrated Impact Assessment Report for Clinical Commissioning Policies

Policy Reference Number	1627		
Policy Title	Mechanical thrombectomy for acute ischaemic stroke		
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Section A - Activity Impact		
Theme	**Questions**	**Comments** (Include source of information and details of assumptions made and any issues with the data)
A1 Current Patient Population & Demography / Growth	A1.1 What is the prevalence of the disease/condition?	A1. 1 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.
	A1.2 What is the number of patients currently eligible for the treatment under the proposed policy?	A1.2 8,000 people per year would fulfil the criteria for consideration for thrombectomy
	A1.3 What age group is the treatment indicated for?	A1.3 All ages

	A1.4 Describe the age distribution of the patient population taking up treatment?	A1.4 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 What is the current activity associated with currently routinely commissioned care for this group?	A1.5 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.
	A1.6 What is the projected growth of the disease/condition prevalence (prior to applying the new policy) in 2, 5, and 10 years?	A1.6 There is no anticipated growth in the numbers of people suffering a stroke as although the incidence is dropping the population is aging. However the population over 65 years is growing by approximately 1.7% per year, so some growth is included.
	A1.7 What is the associated projected growth in activity (prior to applying the new policy) in 2,5 and 10 years?	A1.7 A phased implementation commissioning plan is proposed to allow for development of services and specialists.
	A1.8 How is the population currently distributed	A1.8 The population of people suffering stroke is fairly evenly spread taking

	geographically?	into account age population.
A2 Future Patient Population & Demography	A2.1 Does the new policy: move to a non-routine commissioning position / substitute a currently routinely commissioned treatment / expand or restrict an existing treatment threshold / add an additional line / stage of treatment / other?	A2.1 This policy proposition adds a new treatment to the pathway for a group of patients who have suffered acute ischaemic stroke and fulfil the criteria.
	A2.2 Please describe any factors likely to affect growth in the patient population for this intervention (e.g. increased disease prevalence, increased survival).	A2.2 Aging population as the incidence of stroke increases with age. However due to improved prevention the incidence in <65 has been decreasing
	A 2.3 Are there likely to be changes in geography/demography of the patient population and would this impact on activity/outcomes? If yes, provide details.	A2.3 No
	A2.4 What is the resulting expected net increase or decrease in the number of patients who will access the treatment per year in year 2, 5 and 10?	*A2*.4 Due to the need to set up services the numbers of treatments with thrombectomy will range from 1000 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.

A3 Activity	A3.1 What is the current annual activity for the target population covered under the new policy? Please provide details in accompanying excel sheet. A3.2 What will be the new activity should the new / revised policy be implemented in the target population? Please provide details in accompanying excel sheet. A3.3 What will be the comparative activity for the 'Next Best Alternative' or 'Do Nothing' comparator if policy is not adopted? Please details in accompanying excel sheet.	A3.1 450 completed during 2015/2016 to date (but some unfunded treatment as out of research.) With 120 paid for by the NHS and approx. 200 paid for in 16/17, A3.2 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. For the 5 year period from 17/18 to 21/22 the activity is shown below: - Year 1: 1000 - Year 2: 1750 - Year 3: 2500 - Year 4: 3250 - Year 5: 4000 By year 7 up to total anticipated of 8,000 A3.3 There is no other treatment option for this group of patients other than rehabilitation for disability and good nursing care.
A4 Existing Patient Pathway	A4.1 If there is a relevant currently routinely commissioned treatment, what is the	A4.1 No other pathway beyond thrombolysis except rehab and nursing care

	current patient pathway? Describe or include a figure to outline associated activity. A4.2. What are the current treatment access criteria? A4.3 What are the current treatment stopping points?	 A4.2 N/A A4.3 N/A
A5 Comparator (next best alternative treatment) Patient Pathway	A5.1 If there is a 'next best' alternative routinely commissioned treatment what is the current patient pathway? Describe or include a figure to outline associated activity. A5.2 Where there are different stopping points on the pathway please indicate how many patients out of the number starting the pathway would be expected to finish at each point (e.g. expected number dropping out due to side effects of drug, or number who don't continue to treatment after having test to determine likely success). If possible please indicate likely outcome for patient at each stopping point.	A5.1 N/A A5.2 If eligibility criteria are fulfilled then it would be a rare occasion that a patient would not proceed to treatment.

A6 New Patient Pathway	A6.1 Describe or include a figure to outline associated activity with the patient pathway for the proposed new policy.	A6.1 1. CT scan confirms likely ischaemic stroke 2. CTA confirms due to large artery occlusion (40%) 3. Confirm within 4.5h of stroke onset • If Y, start IV thrombolysis if appropriate whilst reconstruct CTA images for review 4. Moderate to severe stroke? *(on NIHSS assessment tool)* 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**
	A6.2 Where there are different stopping points on the pathway please indicate how many patients out of the number starting the pathway would be expected to finish at each point (e.g. expected number dropping out due to side effects of drug, or number who don't continue to treatment after having test to determine likely success). If possible please indicate likely outcome for patient at each stopping point.	A6.2 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 6h of stroke onset – in practice that means arriving at hospital within 4.5h in order to achieve thrombectomy by 6h. SSNAP data indicate that ¾ of LAO stroke patients present within 4.5h of onset. Applying all these exclusions reduces the number eligible for thrombectomy down to just under 8000 (or 10% of all stroke admissions)
A7 Treatment Setting	A7.1 How is this treatment delivered to the patient? ○ Acute Trust: Inpatient/Day case/ Outpatient ○ Mental Health Provider: Inpatient/Outpatient ○ Community setting ○ Homecare delivery A7.2 Is there likely to be a change in delivery setting or capacity requirements, if so what? *e.g. service capacity*	A7.1 Acute Trust: Inpatient Neuroscience centre. There may be some areas where due to geographical access and transfer times, thrombectomy services may not be within a neuroscience centre but must conform to the service specification standards A7.2 Yes development of services is part of the phased commissioning plan
A8 Coding	A8.1 In which datasets (e.g. SUS/central data	A8.1 SUS, HRG and OPCS and

	collections etc.) will activity related to the new patient pathway be recorded?	outcomes within SSNAP
	A8.2 How will this activity related to the new patient pathway be identified?(e.g. ICD10 codes/procedure codes)	A8.2 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: 1. L71.2 Percutaneous transluminal embolectomy of artery Includes: Percutaneous transluminal thrombectomy of artery: • Y53.- Approach to organ under image control • Z35. Cerebral artery 2. ICD-10 of I63.9 Cerebral infarction, unspecified
A9 Monitoring	A9.1 Do any new or revised requirements need to be included in the NHS Standard Contract Information Schedule?	A9.1 Schedule 6 to be amended
	A9.2 If this treatment is a drug, what pharmacy monitoring is required?	A9.2 N/A
	A9.3 What analytical information /monitoring/ reporting is required?	A9.3 Reporting of activity via SUS with activity and outcomes via SSNAP and QST portal.

	A9.4 What contract monitoring is required by supplier managers? What changes need to be in place?	A9.4 4 monthly outcome reporting (so that it aligns with current audit reporting from SSNAP) Compliance with specification and implementation plan if required
	A9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring?	A9.5 Yes
	A9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy?	A9.6 No
	A9.7 Do you anticipate using Blueteq or other equivalent system to guide access to treatment? If so, please outline. *See also linked question in M1 below*	A9.7 No
Section B - Service Impact		
Theme	**Questions**	**Comments** (Include source of information and details of assumptions made and any issues with the data)
B1 Service Organisation	B1.1 How is this service currently organised? (i.e. tertiary centres, networked provision)	B1.1 Stroke care is organised within provider networks, this intervention will require referral to a

		Neuroscience centre.
	B1.2 How will the proposed policy change the way the commissioned service is organised?	B1.2 Potential for CCGs to unbundle the stroke pathway payment when reduction in length of stay is understood.
B2 Geography & Access	B2.1 Where do current referrals come from?	B2.1 Emergency departments and stroke services. Hospitals with hyper acute stroke units (HASU)
	B2.2 Will the new policy change / restrict / expand the sources of referral?	B2.2 As above There may be a few patients referred from specialists units such as cardiothoracic units, these numbers will be small.
	B2.3 Is the new policy likely to improve equity of access?	B2.3 Yes by increasing the availability of the provision of the service.
	B2.4 Is the new policy likely to improve equality of access / outcomes?	B2.4 Yes as above
B3 Implementation	B3.1 Is there a lead in time required prior to implementation and if so when could implementation be achieved if the policy is agreed?	B3.1 Phased implementation proposed within commissioning implementation plan
	B3.2 Is there a change in provider physical infrastructure required?	B3.2 Potential need for further access to services for thrombectomy when

		the neuroscience centres consider transfer times.
	B3.3 Is there a change in provider staffing required?	B3.3 Increase in number of interventional neuroradiologists or equivalent role to deliver thrombectomy 24/7 and acute aneurysm coiling 7/7.
	B3.4 Are there new clinical dependency / adjacency requirements that would need to be in place?	B3.4 Full immediate access to imaging, critical care and anaesthetics as detailed in the service specification. Approximately ¾ of patients will require an additional ambulance transfer therefore access to critical (critical response times) ambulance transfer.
	B3.5 Are there changes in the support services that need to be in place?	B3.5 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.
	B3.6 Is there a change in provider / inter-provider governance required? (e.g. ODN arrangements / prime contractor)	B3.6 ODN framework already in place for Stroke services
	B3.7 Is there likely to be either an increase or decrease in the number	B3.7 Initially only within neuroscience centres

	of commissioned providers? B3.8 How will the revised provision be secured by NHS England as the responsible commissioner? (e.g. publication and notification of new policy, competitive selection process to secure revised provider configuration)	B3.8 N/A
B4 Collaborative Commissioning	B4.1 Is this service currently subject to or planned for collaborative commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements)	B4.1 No
Section C - Finance Impact		
Theme	**Questions**	**Comments** (Include source of information and details of assumptions made and any issues with the data)
C1 Tariff	C1.1 Is this treatment paid under a national prices*, and if so which?	C1.1 Yes The revenue cost per patient is based on HRG YA12Z. 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:

		1. L71.2 Percutaneous transluminal embolectomy of artery Includes: Percutaneous transluminal thrombectomy of artery: • Y53.- Approach to organ under image control • Z35. Cerebral artery 2. ICD-10 of I63.9 Cerebral infarction, unspecified
	C1.2 Is this treatment excluded from national prices?	C1.2 No
	C1.3 Is this covered under a local price arrangements (if so state range), and if so are you confident that the costs are not also attributable to other clinical services?	C1.3 N/A
	C1.4 If a new price has been proposed how has this been derived / tested? How will we ensure that associated activity is not additionally / double charged through existing routes?	C1.4 N/A
	C1.5 is VAT payable (Y/N) and if so has it been included in the costings?	C1.5 N/A

	C1.6 Do you envisage a prior approval / funding authorisation being required to support implementation of the new policy?	C1.6 No
C2 Average Cost per Patient	C2.1 What is the revenue cost per patient in year 1? C2.2 What is the revenue cost per patient in future years (including follow up)?	C2.1 Year 1 is £13,885 per patient. C2.2 Year 2-5: as year one
C3 Overall Cost Impact of this Policy to NHS England	C3.1 Indicate whether this is cost saving, neutral, or cost pressure to NHS England. C3.2 Where this has not been identified, set out the reasons why this cannot be measured.	C3.1 There would be an estimated Cost Pressure to NHS England of broadly £9,743.6m in Year 1 rising to £45.147m in Year 5. C3.2 N/A
C4 Overall cost impact of this policy to the NHS as a whole	C4.1 Indicate whether this is cost saving, neutral, or cost pressure for other parts of the NHS (e.g. providers, CCGs). C4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as	C4.1 Cost Pressure for NHS England for new intervention. C4.2 Cost Pressure for NHS England specialised

	a whole. C4.3 Where this has not been identified, set out the reasons why this cannot be measured. C4.4 Are there likely to be any costs or savings for non NHS commissioners / public sector funders?	services. The cost saving for CCGs is £6.2m in year 1 rising to £28.9m in year 5 C4.3 N/A C4.4 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
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*	C5.1 Request for funding
C6 Financial Risks Associated with Implementing this Policy	C6.1 What are the material financial risks to implementing this policy?	C6.1 There may be risks around the implementation plan (Commissioning) being proposed and how quickly the current services can be mobilised to meet the requirements of each phase: • Phase I – all neuroscience centres who currently coil aneurysms who have a HASU on site can offer thrombectomy as long as they can deliver an

		implementation plan that is endorsed and approved by regional commissioners Or access via via a networked arrangement pending expansion in trained operators. • Phase II – an intermediate position by September 2018. • Phase III – fully meets the specification – an agreed development plan is required by September 2017 – trajectory subject to HEE plan for delivering trained for neurointervention to cover 24/7 thrombectomy/coiling rotas 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 either under, or overstate future activity. There are ongoing randomised trials that may extend the evidence base in terms of reducing the proportion of thrombectomy exclusions. For instance: • 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%). Together these ongoing trials could increase numbers eligible by ~35%
	C6.2 Can these be mitigated, if so how?	C6.2 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). This should be considered under a collaborative commissioning type arrangement if possible
	C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	C6.3 Phased implementation as per the commissioning plan.
C7 Value for Money	C7.1 What evidence is available that the treatment is cost effective? *e.g. NICE appraisal, clinical trials or peer reviewed literature*	C7.1 NICE- Mechanical clot retrieval for treating acute ischaemic stroke - Interventional procedures guidance [IPG548] Published date: February 2016 Sentinel Stroke National Audit Programme Cost and Cost-effectiveness analysis 2016
	C7.2 What issues or risks are associated with this assessment? *e.g. quality or availability of evidence*	C7.2 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 policy? *e.g. Transitional costs, periodical costs*	C8.1 PACS workstations at home for all neurointerventionists on the coiling/thrombectomy rota & with full connectivity to all hospital PACS systems referring into their service

	C8.2 If so, confirm the source of funds to meet these costs.	(circa £12,000 per interventionist) C8.2 N/A