NHS England

Integrated Impact Assessment Report for Service Specifications			
Service Specification Reference Number	1640		
Service Specification Title	Cystinosis (all ages) Proposal **for routine commission** (source A3.1)		
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Finance Lead	Keith Moulds	**Analytical Lead**	NA

Integrated Impact Assessment – Index

Section A – Activity	Section B - Service	Section C – Finance
A1 Current Patient Population & Demography / Growth	B1 Service Organisation	C1 Tariff
A2 Future Patient Population & Demography	B2 Geography & Access	C2 Average Cost per Patient
A3 Activity	B3 Implementation	C3 Overall Cost Impact of this service specification to NHS England
A4 Patient Pathway	B4 Collaborative Commissioning	C4 Overall cost impact of this service specification to the NHS as a whole
A5 Service Setting		C5 Funding
A6 Coding		C6 Financial Risks Associated with Implementing this service specification
A7 Monitoring		C7 Value for Money
		C8 Cost Profile

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.	The prevalence of cystinosis is between 1 per 100,000 and 1 per 200,000 live births. There are c165 patients in England who are currently receiving treatment with systemic cysteamine to treat cystinosis. Infantile Nephropathic; the severest form accounting for about 90-95% of all cases 2/3 new patients per year. Juvenile (late onset) Nephropathic; accounting for about 3-5% of cases 2/3 new cases per year *Source: Service Specification Proposition section 3.1*
A1.2 Number of patients currently eligible for the service according to the proposed service specification commissioning criteria.	165 *Source: Company information from mercaptamine policy validated by PWG* Please specify
A1.3 Age group for which the service is proposed according to the service specification commissioning criteria.	**All ages** Please specify Approximately a 53:47 split between adults and children, slightly more children have been identified.
A1.4 Age distribution of the patient population eligible according to the proposed service specification commissioning criteria	In paediatric population age distribution birth to 18 years when transitioned to adult services. *Source: data from individual centres* Please specify

<table>
<tr><td>A1.5 How is the population currently distributed geographically?</td><td><u>Unevenly</u>
If unevenly, estimate regional distribution by %:
<table><tr><td>North</td><td>33%</td></tr><tr><td>Midlands & East</td><td>43%</td></tr><tr><td>London</td><td>22%</td></tr><tr><td>South</td><td><2%</td></tr></table>Please specify
Based on RaDaR data of centres looking after patients</td></tr>
<tr><td colspan="2">A2 Future Patient Population & Demography</td></tr>
<tr><td>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?</td><td><u>Increasing</u>
Up to 3 new diagnosis in children expected each year
A late onset diagnosis can be expected in a negligible number of adult patients each year, may be one patient
If other,
Source: Service specification proposition section 3.1</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>
Please specify
Source: Service specification 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 the service, according to the proposed service specification 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>+12</td></tr></table></td></tr>
</table>

Are these numbers in line with ONS growth assumptions for the age specific population? If not please justify the growth assumptions made.	<table><tr><td>YR5 +/-</td><td>+15</td></tr><tr><td>YR10 +/-</td><td>+30</td></tr></table> *Source: Service specification proposition section 3.1* **No** Cystinosis is a rare inherited disease. The growth assumptions are based on a UK study on the incidence of genetic disorders in the West Midlands which was carried out between 1981-1991. The study recorded 21 new cases of cystinosis born in this time period (Source: Hutchesson, Bundey, Preece, Hall & Green 1998). An incidence (accounting for mortality) of net +3 patients per year has been assumed based on this study.
A3 Activity	
A3.1 What is the purpose of new service specification?	**Provide service specification document for a service already commissioned by NHS England in accordance with 'The Manual' but without a published specification** *PSSAG (Prescribed Specialised Services Advisory Group) Please specify Cystinosis is a very rare inherited lysosomal storage disease presenting in infancy (95% of cases) with severe kidney disease but subsequently involving multiple organs (eyes, thyroid, liver, diabetes, muscle deterioration). It occurs when the mechanism removing excess cystine, an amino acid, breaks down. It then accumulates within body cells preventing these cells from functioning correctly. Patients often present to paediatric nephrology services although multi organ disease requires multi-speciality input. Effective drug therapy and renal transplantation now allows survival into the fifth decade.

<table>
<tr><td></td><td>There is currently no dedicated specialist service for Cystinosis in England. Local care services focussed in paediatric nephrology units. Current care is fragmented with major geographical variability in care quality. Early initiation of cysteamine therapy can significantly postpone, or even prevent complications of the disease. Poorly coordinated care results in patients attending multiple clinics on different days at different sites. Since the use of cysteamine and the introduction of renal replacement therapy in paediatric populations, patients with cystinosis are increasingly surviving into adulthood. However, there are few transition services from childhood to adult clinics and limited adult services. Clinical inexperience compromises care especially within adult services. Better recognition and treatment of late-term complications in adulthood will improve long-term outcomes in patients.

This proposal for the development of services to provide an integrated multi-disciplinary one stop service for both paediatric and adult patients to ensure consistent and quality service is delivered. The specification describes a hub and spoke model of care.</td></tr>
<tr><td>A3.2 What is the annual activity associated with the existing pathway for the eligible population?</td><td>The annual activity is shown in the table below. This is the estimated number of people diagnosed and eligible for a treatment.
<table><tr><td>Year</td><td>Activity</td></tr><tr><td>0</td><td>165</td></tr><tr><td>1</td><td>168</td></tr><tr><td>2</td><td>171</td></tr><tr><td>3</td><td>174</td></tr><tr><td>4</td><td>177</td></tr><tr><td>5</td><td>180</td></tr></table></td></tr>
</table>

	Source: *required* Please specify
A3.3 What is the estimated annual activity associated with the proposed service specification proposition pathway for the eligible population?	Baseline 165 *Source:* *required* Please specify It is expected that all patients with cystinosis will be managed by one of the HSS.
A4 Patient Pathway	
A4.1 **Patient pathway** Describe the current patient pathway and service.	Cystinosis is likely to be diagnosed by a consultant paediatric nephrologist. These consultants' practice in many hospitals around the England but are organised through 10 tertiary paediatric nephrology centres. Similarly, adult patients are currently managed in any of the 41 adult renal units across England. There is also some clustering of activity around a small numbers of centres with expertise. *Source:* *SWG*
A4.2. What are the current service access and stopping criteria?	Nephropathic cystinosis (affecting other areas of the body including the kidneys, eyes, growth, brain and muscles): Referral from local GP services to a local paediatrician or a nephrologist. If cystinosis is suspected, then a referral is made to a consultant nephrologist based at a tertiary centre with expertise in cystinosis for diagnosis. Treatment is initiated once there is confirmed nephropathic cystinosis upon testing (LCL levels test; corneal cystine crystals visible under slit lamp; possible genetic analysis of CTNS gene). Non-nephropathic cystinosis (affecting the eyes only): Referral from GP to local ophthalmologist. Where there are ocular manifestations of cystinosis, referral is made to a consultant ophthalmologist and

	consultant nephrologist at a tertiary centre with expertise in cystinosis. Treatment is initiated once there is confirmed ocular cystinosis upon testing ((LCL levels test; corneal cysteine crystals visible under slit lamp; possible genetic analysis of CTNS gene; no clinical presentation with Fanconi syndrome). For follow-up, patients are mainly seen by the nephrologist, endocrinologist, neurologist and for the eye condition an ophthalmologist. Allied health professionals also involved. Frequency depends on the clinical status of the patient and is therefore is variable. Seeing the treating physician a couple of times a year is common. Patients continue in the pathway life-long *Source:* required
A4.3 What percentage of the total eligible population are: a) Referred b) Meet any existing criteria for care c) Considered to meet any existing exclusion criteria	If not known, please specify a) 100 b) 100 c) 0 Because of the serious clinical consequences of the disease, we believe that all eligible patients will be referred at some point, depending on the speed of diagnosis. There are no exclusion criteria. *Source:* required
A4.4 What percentage of the total eligible population is expected to: a) Be referred to the proposed service b) Be eligible for care according to the proposed criteria for the service c) Take up care according to the proposed criteria for the service d) Continue care according to the proposed criteria for the service?	If not known, please specify a) 100 b) 100 c) 95 d) 90% *Source:* required

A4.5 Specify the nature and duration of the proposed new service or intervention.	**Life long** For time limited services, specify frequency and/or duration. The proposal is to set up a small number of highly specialised centres with expertise in the diagnosis and management of patients with cystinosis which is complex and involves the provision of comprehensive care by a team of health care professionals. Shared care arrangements using nationally standardised protocols will be established with the patient's local renal centres, which in turn will deliver routine children's care with the benefit of easy access and communication with the highly specialised paediatric cystinosis service. Adults with cystinosis require access to many of the same services available in the paediatric centres although diagnosis will already be secure in most cases. Kidney disease is typically more advanced in adults and many will have established kidney failure and require renal replacement therapy by dialysis or transplantation. Significant numbers of patients already survive into adulthood with relatively well-preserved renal function and continuing renal Fanconi syndrome. Routine care for chronic kidney disease, including renal replacement therapy, will be provided by local nephrology services. *Source:* *Service specification 2.1*
A5 Service Setting	
A5.1 How is this service delivered to the patient?	*Select all that apply:* Emergency/Urgent care attendance ☐ Acute Trust: inpatient ☐

	<table><tr><td>Acute Trust: day patient</td><td>☐</td></tr><tr><td>Acute Trust: outpatient</td><td>☒</td></tr><tr><td>Mental Health provider: inpatient</td><td>☐</td></tr><tr><td>Mental Health provider: outpatient</td><td>☐</td></tr><tr><td>Community setting</td><td>☐</td></tr><tr><td>Homecare</td><td>☐</td></tr><tr><td>Other</td><td>☐</td></tr></table>Please specify:
A5.2 What is the current number of contracted providers for the eligible population by region?	<table><tr><td>NORTH</td><td>0</td></tr><tr><td>MIDLANDS & EAST</td><td>0</td></tr><tr><td>LONDON</td><td>0</td></tr><tr><td>SOUTH</td><td>0</td></tr></table>
A5.3 Does the proposition require a change of delivery setting or capacity requirements?	**yes** Please specify: The proposition is to establish a small number of highly specialised centres across the country with expertise in the management of patients with cystinosis. Patients are currently managed in one of the 10 paediatric nephrology centres in England or one of the 41 adult nephrology units. *Source:* SWG
A6 Coding	

A6.1 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 * ☒ 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** ☒ **If National Return, Clinical database or other selected, please specify: Data will be submitted to the UK Renal Registry of the Renal Association and its Rare Kidney Disease Registry (RADAR) for audit purposes. Other data points have been agreed and will be reported to the HSS commissioners annually for review at a national audit meeting of all centres.
A6.2 Specify how the activity related to the new patient pathway will be identified.	*Select all that apply:* OPCS v4.8 ☒ ICD10 ☒ Service function code ☒ Main Speciality code ☒ HRG ☒

<table>
<tr><td></td><td><table><tr><td>SNOMED</td><td>☐</td></tr><tr><td>Clinical coding / terming methodology used by clinical profession</td><td>☐</td></tr></table></td></tr>
<tr><td>A6.3 Identification Rules for Drugs:
How are any drug costs captured?</td><td><u>Not applicable</u>
If already specified in the current NHS England Drug / Devices List, please specify drug name and indication for all that apply:
If drug(s) NOT already been specified in the current NHS England Drug List please give details of action required and confirm that this has been discussed with the pharmacy lead:
NICE CSP on the use of mercaptamine is corneal cystinosis, subject to separate funding arrangements if agreed.
All patients are on oral cysteamine therapy. Early initiation of therapy can significantly postpone, or even prevent complications of the disease. Poorly coordinated care results in patients attending multiple clinics on different days at different sites. Cystagon is currently paid for by pass through to NHS England and this would not change, patients would still have drugs dispensed/prescribed locally.</td></tr>
<tr><td>A6.4 Identification Rules for Devices:
How are device costs captured?</td><td><u>Not applicable</u>
If device(s) covered by an existing category of HCTED please specify the Device Category (as per the National Tariff Payment System Guidance) for all that apply:
If device(s) 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.</td></tr>
<tr><td>A6.5 Identification Rules for Activity:
How are activity costs captured?</td><td><u>Already captured by an existing specialised service line (NCBPS code) within the PSS Tool but needs amendment</u></td></tr>
</table>

	If activity costs are already captured please specify the specialised service code and description (e.g. NCBPS01C Chemotherapy). NCBPS23S CHILDRENS SERVICES – RENAL New service line codes for both adult and paediatric services are needed If activity costs are already captured please specify whether this service needs a separate code. **Yes** If the activity is captured but the service line needs amendment please specify whether the proposed amendments have been documented and agreed with the Identification Rules team. Not yet agreed If the activity is not captured please specify whether the proposed identification rules have been documented and agreed with the Identification Rules team.
A7 Monitoring	
A7.1 **Contracts** Specify any new or revised data flow or data collection requirements, needed for inclusion in the NHS Standard Contract Information Schedule. Please identify any excluded drugs or devices relevant to the service and their current status with regard to NHS England specialised services commissioning.	**Yes - other** Please specify Cystinosis services E72.0 adults and paediatrics will be reported against a (to be agreed) new service line.
A7.2 **Business intelligence** Is there potential for duplicate reporting?	**Yes** If yes, please specify mitigation: Monitoring via the established processes for Highly Specialised Services via the HSS Informatics lead.

A7.3 **Contract monitoring** Is this part of routine contract monitoring?	<u>**No**</u> If no, please specify contract monitoring requirement: The service specification would need to be included in the NHS Standard Contract Information Schedule. Data will be provided to supplier managers via the HSS informatics lead.
A7.4 **Dashboard reporting** Specify whether a dashboard exists for the proposed service?	<u>**No**</u> If yes, specify how routine performance monitoring data will be used for dashboard reporting. We would ensure performance monitoring is established in line with all HSS with annual outcome reporting If no, will one be developed? No monitoring of the agreed outcomes will be via the HSS team, no plans to develop a dashboard
A7.5 **NICE reporting** Are there any directly applicable NICE or equivalent quality standards which need to be monitored in association with the new service specification?	<u>**No**</u> If yes, specify how performance monitoring data will be used for this purpose.
Section B - Service Impact	
B1 Service Organisation	
B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.)	Children are currently managed within the 10 specialised paediatric nephrology centres in England. Adult patients are managed in one of the 41 adult nephrology centres. Many adults will have established kidney failure and require renal replacement therapy by dialysis or transplantation. Current care is fragmented with major geographical variability in care quality.

	Routine care for chronic kidney disease, including renal replacement therapy, is provided by local nephrology services and this will continue in the new model for care of adult patients with cystinosis. There are no current care guidelines and no functional registry resulting in limited audit or R&D. Since the use of cysteamine and the introduction of renal replacement therapy in paediatric populations, patients with cystinosis are increasingly surviving into adulthood. However, there are few transition services from childhood to adult clinics and limited adult services. Clinical inexperience compromises care especially within adult services. Better recognition and treatment of late-term complications in adulthood will improve long-term outcomes in patients. *Source:* *service specification*
B1.2 Will the specification change the way the commissioned service is organised?	**Yes** Please specify: Highly specialised management and oversight of patients will be from a small number of centres. Patients will be reviewed at least annually in the HSS. *Source:* *service specification*
B1.3 Will the specification require a new approach to the organisation of care?	**Implement a new model of care** Please specify: The service model will balance the needs of patients and their families / carers to receive routine care that might involve frequent visits to local centres (hospitals / spokes) with the need for regular but less frequent visits (e.g. 6-12 monthly) to highly specialised, multi-disciplinary, and multi-professional clinics with a critical mass of expertise and experience of care for patients with cystinosis across all age groups. The model will apply equally to adult and children's services, although the role of the centre may vary for the two groups of patients. Patient transition will involve a period of joint care from paediatric and adult services, multi-

	disciplinary teams to offer care that recognises that transition patients may have additional developmental needs.
B2 Geography & Access	
B2.1 Where do current referrals come from?	*Select all that apply:* GP ☒ Secondary care ☒ Tertiary care ☒ Other ☐ Please specify: PWG
B2.2 What impact will the new service specification have on the sources of referral?	**<u>No impact</u>** Please specify: The sources of referral are not expected to change
B2.3 Is the new service specification likely to improve equity of access?	**<u>Increase</u>** Please specify: Annual analysis will be undertaken to ensure that access to the service is equitable across England. The services will improve access to expert diagnosis and ongoing management advice. Currently patients are managed in a greater number of centres than will be the case in the future. The HSS will work with local renal centres to support the ongoing care for patients. *Source: Equalities Impact Assessment*

B2.4 Is the new service specification likely to improve equality of access and/or outcomes?	**Increase** Please specify: All patients will have access to highly specialised services. At present patients have multiple attendances across potentially many sites. The man advantage of this proposal is the lead centres will have the expertise for treating this rare condition. *Source: Equalities Impact Assessment*
B3 Implementation	
B3.1 Will commissioning or provider action be required before implementation of the proposition can occur?	**Provider selection action** Please specify:
B3.2 **Time to implementation:** Is a lead-in time required prior to implementation?	**Yes - go to B3.3** If yes, specify the likely time to implementation: 6 months
B3.3 **Time to implementation:** If lead-in time is required prior to implementation, will an interim plan for implementation be required?	**No - go to B3.4** If yes, outline the plan: For the service, if mercaptamine is agreed for NHS funding from a point earlier than the highly specialised services would be in place then an interim management plan will be needed,
B3.4 Is a change in provider physical infrastructure required?	**No** Please specify:
B3.5 Is a change in provider staffing required?	**Yes**

<table>
<tr><td></td><td>Please specify:
A service implementation plan would be required as part of the provider selection process.</td></tr>
<tr><td>B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?</td><td>Yes
Please specify:
Major renal units will have services in place, an additional requirement would be to establish transition pathways between the paediatric and adult services.</td></tr>
<tr><td>B3.7 Are there changes in the support services that need to be in place?</td><td>Yes
Please specify:
There will be a need to ensure support services were all in place prior to commencement of the service</td></tr>
<tr><td>B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)</td><td>No
Please specify:</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>Increase
Please complete the table:
<table>
<tr><th>Region</th><th>Current no. of providers</th><th>Future
State expected range</th><th>Provisional or confirmed</th></tr>
<tr><td>North</td><td>0</td><td>1-2</td><td>P</td></tr>
<tr><td>Midlands & East</td><td>0</td><td>1-2</td><td>P</td></tr>
<tr><td>London</td><td>0</td><td>1-2</td><td>P</td></tr>
<tr><td>South</td><td>0</td><td>1-2</td><td>P</td></tr>
</table></td></tr>
</table>

	<table><tr><td>Total</td><td>0</td><td>4-6</td><td>P</td></tr></table>Please specify: The changes in the service specification involve the designating of six specialist centres three for the Paediatric service and three for the adult service. The objective is for patients to be seen at these centres and be able to receive their care in fewer visits to Hospital.
B3.10 Specify how revised provision will be secured by NHS England as the responsible commissioner.	*Select all that apply:*<table><tr><td>Publication and notification of new service specification</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>Please specify:
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:

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

Select all that apply:

Drugs	Not separately charged – part of local or national tariffs	☒
	Excluded from tariff – pass through	☒
	Excluded from tariff - other	☐
Devices	Not separately charged – part of local or national tariffs	☐
	Excluded from tariff (excluding ZCM) – pass through	☐
	Excluded from tariff (excluding ZCM) – other	☐
	Via Zero Cost Model	☐
Activity	Paid entirely by National Tariffs	☐
	Paid entirely by Local Tariffs	☐
	Partially paid by National Tariffs	☒
	Partially paid by Local Tariffs	☐
	Part/fully paid under a Block arrangement	☒
	Part/fully paid under Pass-Through arrangements	☐

	Part/fully paid under Other arrangements ☐
C1.2 **Drug Costs** 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. NB discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.	Cysteamine eye drops (a) Current unlicensed preparation, Guy's Hospital Pharmacy (b) Cystadrops Oral Cysteamine (a) Cystagon (Orphan Europe), approved (b) Procysbi (Chiesi), applications from company
C1.3 **Device Costs** 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. NB: Discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.	N/A
C1.4 **Activity Costs covered by National Tariff** List all the HRG codes, HRG descriptions, national tariffs (excluding MFF), volume and other key costs (e.g. specialist top up %)	The activity connected to this service will continue be paid for under tariff. Most of the activity is out patient. The adult service is paid for by CCGs and the Paeds service paid for by NHSE. For adults there is a national tariff and for Paeds it is covered by local prices The service specification does not propose any change to the way activity is charged or recorded for or the responsible commissioner.
C1.5 **Activity Costs covered by Local Tariff**	The activity connected to this service will continue be paid for under tariff.

<table>
<tr><td>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.</td><td>Most of the activity is out patient. The adult service is paid for by CCGs and the paediatric service paid for by NHSE. For adults there is a national tariff and for paediatrics it is covered by local prices

The service specification does not propose any change to the way activity is charged or recorded for or the responsible commissioner.</td></tr>
<tr><td>C1.6 Other Activity Costs not covered by National or Local Tariff
Include descriptions and estimates of all key costs.</td><td>Six centres are planned to be selected. The designated centres will be reimbursed for additional staffing above tariff for providing the service.
From work carried out with providers this is calculated as £100k per centre per year which will be paid as a block.

The payment will be triggered by the centre showing that it has achieved full service implementation according to the service specification. A provider selection will be required.

The total cost is £605k including access to the RaDar database.</td></tr>
<tr><td>C1.7 Are there any prior approval mechanisms required either during implementation or permanently?</td><td><u>No</u>
Please specify:</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>£2.1k</td></tr><tr><td>YR2</td><td>£3.5k</td></tr><tr><td>YR3</td><td>£3.5k</td></tr></table></td></tr>
</table>

<table>
<tr><td>Are there any changes expected in year 6-10 which would impact the model?</td><td><table><tr><td>YR4</td><td>£3.4k</td></tr><tr><td>YR5</td><td>£3.4k</td></tr></table>If yes, please specify:</td></tr>
<tr><td colspan="2">C3 Overall Cost Impact of this Service specification to NHS England</td></tr>
<tr><td>C3.1 Specify the budget impact of the proposal on NHS England in relation to the relevant pathway.</td><td><u>The impact of setting up 6 centres at a cost of £100k each per year + access to the RaDar database will be £605k per year from year2 . In year 1 the expected start date is September and the cost would be £355k. There will also be a minimal impact on activity</u>
Please specify:</td></tr>
<tr><td>C3.2 If the budget impact on NHS England cannot be identified set out the reasons why this cannot be measured.</td><td>NA</td></tr>
<tr><td>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?</td><td>NA</td></tr>
<tr><td colspan="2">C4 Overall cost impact of this service specification to the NHS as a whole</td></tr>
<tr><td>C4.1 Specify the budget impact of the proposal on other parts of the NHS.</td><td>Budget impact for CCGs:
<u>Cost neutral</u>
Budget impact for providers:
<u>Cost neutral</u>
Please specify:</td></tr>
</table>

C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	**<u>Cost pressure</u>** Please specify: Cost of additional staffing at designated centres
C4.3 Where the budget impact is unknown set out the reasons why this cannot be measured	NA
C4.4 Are there likely to be any costs or savings for non-NHS commissioners and/or public sector funders?	**<u>Unknown</u>** Please specify: It is expected that improving the model of care will reduce multiple attendances and that overall the model will be more efficient over time. This will impact on multiple responsible authorities. However this will be hard to test but could e subject to audit.
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.	Delivery group / SMT reserve
C6 Financial Risks Associated with Implementing this Service specification	
C6.1 What are the material financial risks to implementing this service specification?	NA
C6.2 How can these risks be mitigated?	NA

<table>
<tr><td>C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?</td><td>NA</td></tr>
<tr><td>C6.4 What scenario has been approved and why?</td><td>NA</td></tr>
<tr><td colspan="2">C7 Value for Money</td></tr>
<tr><td>C7.1 What published evidence is available that the service is cost effective as evidenced in the evidence review?</td><td><u>Published evidence indicates service specification has the potential to be cost-effective</u>
Please specify:</td></tr>
<tr><td>C7.2 Has other data been identified through the service specification development relevant to the assessment of value for money?</td><td>Select all that apply:
<table>
<tr><td>Available pricing data suggests the service specification is equivalent cost compared to current/comparator service specification</td><td>☐</td></tr>
<tr><td>Available pricing data suggests the service is lower cost compared to current/comparator treatment</td><td>☐</td></tr>
<tr><td>Available clinical practice data suggests the new service specification has the potential to improve value for money</td><td>☐</td></tr>
<tr><td>Other data has been identified</td><td>☐</td></tr>
<tr><td>No data has been identified</td><td>☐</td></tr>
<tr><td>The data supports a high level of certainty about the impact on value</td><td>☐</td></tr>
<tr><td>The data does not support a high level of certainty about the impact on value</td><td>☐</td></tr>
</table></td></tr>
</table>

	Please specify:
C8 Non-Recurrent Costs	
C8.1 Are there non-recurrent revenue costs associated with this service specification?	**No** If yes, please specify and indicate whether these would be incurred or passed through to NHS England: If the costs are to be passed through to NHS England please indicate whether this has been taken into account in the budgetary impact.
C8.2 Are there any non-recurrent provider capital costs associated with the service specification?	**No** If yes, please specify and indicate with there is a separate source of funding identified (commissioners cannot reimburse capital costs).