Integrated Impact Assessment Report for Clinical Commissioning Policies			
Policy Reference Number	1840		
Policy Title	Sapropterin for phenylketonuria all ages, interim pending NICE guidance Proposal **for routine commissioning** (ref A3.1)		
Lead Commissioner	Joan Ward	**Clinical Lead**	Maureen Cleary
Finance Lead	Justine Stalker-Booth	**Analytical Lead**	Justine Stalker-Booth

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 Policy to NHS England
A4 Existing Patient Pathway	B4 Collaborative Commissioning	C4 Overall cost impact of this policy to the NHS as a whole
A5 Comparator (next best alternative treatment) Patient Pathway		C5 Funding
A6 New Patient Pathway		C6 Financial Risks Associated with Implementing this Policy
A7 Treatment Setting		C7 Value for Money
A8 Coding		C8 Cost Profile
A9 Monitoring		

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 policy documents or a source for the information is provided. • Where assumptions are included where data is not available, this is specified.

Section A - Activity Impact	
A1 Current Patient Population & Demography / Growth	
A1.1 Prevalence of the disease/condition.	Click here to enter text. Phenylketonuria (PKU) is a rare genetic disorder in which a particular substance called phenylalanine (which is found in some food proteins) cannot be broken down and accumulates in the body. Some patients have a milder form of the disorder and some have a severe form. Phenylalanine (Phe) is extremely toxic to the brain and untreated PKU patients have profound brain damage with a very low IQ, seizures and behavioural and social problems, other motor difficulties and autism. PKU patients are able to tolerate only very small amounts of natural protein as it contains phenylalanine which increases the phe level in their bodies and leads to profound brain damage. The drug sapropterin enables PKU patients to eat more natural protein without risking brain damage. Only patients who have a specific mutation respond to this treatment. In England this is estimated at 25-35% of the patient population. Although PKU is identified through the new-born screening programme, the epidemiology is limited in relation to this disease. The incidence of PKU varies by population and in England it is estimated at 1 per 10,000/14,000 giving a prevalence of 4,000 to 5,600. In 2015-16, the incidence rate of positive screening tests for phenylketonuria was 0.013% (87 babies tested positive and 672,766 babies were tested). It is likely that the number of individuals under regular follow up is about 2000. It is estimated that only about 25-30% of the English population are likely to respond to sapropterin giving an estimate of 500 eligible individuals of all ages. It is anticipated that the number who would, over time, access treatment is less than this figure, approximately 300-330. It is thought that this population is split evenly between adults and children. Approximately 27-29 babies from the PKU population, identified through new born screening will have the genetic mutation that enables them to respond to sapropterin.

<table>
<tr><td>A1.2 Number of patients currently eligible for the treatment according to the proposed policy commissioning criteria.</td><td>323
Source: Policy proposition
Please specify
Click here to enter text.</td></tr>
<tr><td>A1.3 Age group for which the treatment is proposed according to the policy commissioning criteria.</td><td><u>All ages</u>
Please specify
Click here to enter text.</td></tr>
<tr><td>A1.4 Age distribution of the patient population eligible according to the proposed policy commissioning criteria</td><td>It is assumed that approximately 55% of patients in the initial cohort will be under 19 years of age.
Source: Policy proposition
Please specify
Per ONS statistical analysis</td></tr>
<tr><td>A1.5 How is the population currently distributed geographically?</td><td><u>unknown</u>
If unevenly, estimate regional distribution by %:<table><tr><td>North</td><td>enter %</td></tr><tr><td>Midlands & East</td><td>enter %</td></tr><tr><td>London</td><td>enter %</td></tr><tr><td>South</td><td>enter %</td></tr></table>Source: Policy Proposition section 6
Please specify
Click here to enter text.</td></tr>
<tr><td colspan="2">A2 Future Patient Population & Demography</td></tr>
</table>

<table>
<tr><td>A2.1 Projected changes in the disease/condition epidemiology, such as incidence or prevalence (prior to applying the new policy) in 2, 5, and 10 years?</td><td><u>Constant</u>

If other, Click here to enter text.
Source: Policy Proposition section 6</td></tr>
<tr><td>A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?</td><td><u>No</u>
Please specify
Click here to enter text.
Source: Policy Proposition section 6/other</td></tr>
<tr><td>A2.3 Expected net increase or decrease in the number of patients who will be eligible for the service, according to the proposed service specification commissioning criteria, per year in years 2-5 and 10?

Are these numbers in line with ONS growth assumptions for the age specific population? If not please justify the growth assumptions made.</td><td><table><tr><td>YR2 +/-</td><td>24</td></tr><tr><td>YR3 +/-</td><td>48</td></tr><tr><td>YR4 +/-</td><td>72</td></tr><tr><td>YR5 +/-</td><td>96</td></tr><tr><td>YR10 +/-</td><td>216</td></tr></table>
Source: Service specification proposition section 3.1

Choose an item.
This is the patient cohort identified annually through newborn screening and the subsequent Sapropterin Loading test.</td></tr>
<tr><td colspan="2">A3 Activity</td></tr>
<tr><td>A3.1 What is the purpose of new policy?</td><td><u>Confirm routine commissioning position of an additional new treatment</u></td></tr>
</table>

	Please specify Click here to enter text.
A3.2 What is the annual activity associated with the existing pathway for the eligible population?	323 *Source: required* Please specify This is number of patients known to services who would be responders to treatment. These patients are currently following a low protein diet and dietary supplements.
A3.3 What is the estimated annual activity associated with the proposed policy proposition pathway for the eligible population?	323 *Source: required* Please specify Click here to enter text.
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.	Not applicable *Source: required* Please specify Click here to enter text.
A4 Existing Patient Pathway	
A4.1 **Existing pathway:** Describe the relevant currently routinely commissioned: • Treatment or intervention • Patient pathway • Eligibility and/or uptake estimates.	Patients are identified with PKU through the new born screening programme. Most patients are referred to metabolic services and receive specialist dietetic input to help them manage the diet. This diet is very restricted; patients are able to eat very low levels of natural protein without the risk of brain damage and must take synthetic protein supplements up to 3 times a day. Patients can find these supplements

	difficult to tolerate. These food supplements are funded by CCGs. Specialist dieticians monitor patients' weekly through blood spot monitoring and advise on food and synthetic protein supplement intake accordingly. Patients have to monitor their PHE levels weekly. Compliance with diet reduces with age and about 50% of adults leave treatment. Sapropterin is a medicine that reduces the PHE levels. Treatment aims to lower the blood PHE levels to close to or below the European Guideline levels (therapeutic ranges are: 120-360 µmol/l up to 12 years, 13 years onwards 120-600 µmol/l, women who are planning a pregnancy 120-360 µmol/l). For each 100 µmol/L increases in blood PHE there is a predicted reduction in IQ of 1.3 to 3.1 points (Waisbren et al). Not all patients with PKU will be able to take this drug; it is estimated that between 25-35% of patients have the genetic mutation that responds to this treatment. In England the estimate of the number of patients who would be responsive to sapropterin and would take up the treatment option which would include the requirement for regular weekly monitoring is 300-330. *Source:* *required*
A4.2. What are the current treatment access and stopping criteria?	The diet is offered to all patients with PKU. Patients who wish to be prescribed low protein foods and synthetic protein have to comply with the Phe monitoring by a specialist centres. *Source:* *required*
A4.3 What percentage of the total eligible population is expected to: a) Be clinically assessed for treatment b) Be considered to meet an exclusion criteria following assessment	If not known, please specify Click here to enter text. a) All patients with PKU are offered the dietary treatments and synthetic protein supplements at birth. b) 50% patients tend to exit themselves from treatment when they are unable to comply with the diet and the monitoring. c) 100% initiate dietary treatment

c) Choose to initiate treatment d) Comply with treatment e) Complete treatment?	d) 50 % of patients comply with treatment e) Treatment is lifelong *Source: required*
A5 Comparator (next best alternative treatment) Patient Pathway (NB: comparator/next best alternative does not refer to current pathway but to an alternative option)	
A5.1 **Next best comparator**: Is there another 'next best' alternative treatment which is a relevant comparator? *If yes, describe relevant* • *Treatment or intervention* • *Patient pathway* • *Actual or estimated eligibility and uptake*	**No** If yes, Click here to enter text. *Source: required*
A5.2 What percentage of the total eligible population is estimated to: a) Be clinically assessed for treatment b) Be considered to meet an exclusion criteria following assessment c) Choose to initiate treatment d) Comply with treatment e) Complete treatment?	Total estimated eligible a) b) c) d) e) *Source: required*

A6 New Patient Pathway	
A6.1 What percentage of the total eligible population is expected to: a) clinically assessed for treatment a) Be considered to meet an exclusion criteria following assessment b) Choose to initiate treatment c) Comply with treatment d) Complete treatment?	If not known, please specify Click here to enter text. a) 60-70 % of all patients with PKU are likely to ask to be tested b) 70-75% of patients will not have the genetic mutation that enables them to respond to the drug appropriately. c) 25-35% are likely to be responders to the drug and to wish to continue in treatment d) 25-30% e) Treatment is lifelong *Source: required*
A6.2 Specify the nature and duration of the proposed new treatment or intervention.	**Life long** For time limited treatments, specify frequency and/or duration. Click here to enter text. *Source: required*

A7 Treatment Setting

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

Select all that apply:

Emergency/Urgent care attendance	☐
Acute Trust: inpatient	☐
Acute Trust: day patient	☐
Acute Trust: outpatient	☒
Mental Health provider: inpatient	☐
Mental Health provider: outpatient	☐
Community setting	☐
Homecare	☒
Other	☐

Please specify:

Click here to enter text.

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

NORTH	7
MIDLANDS & EAST	5
LONDON	3
SOUTH	4

Although NHS England is the commissioner for metabolic services, much of the activity relating to this specialty sits with CCG portfolios. The table above reflects that provider landscape; some providers provide adult and paediatric services.

A7.3 Does the proposition require a change of delivery setting or capacity requirements?	**No** Please specify: *Source:* *required*
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 * ☒ 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: Click here to enter text.
A8.2 Specify how the activity related to the new patient pathway will be identified.	*Select all that apply:*

	<table><tr><td>OPCS v4.8</td><td>☐</td></tr><tr><td>ICD10</td><td>☐</td></tr><tr><td>Treatment function code</td><td>☐</td></tr><tr><td>Main Speciality code</td><td>☐</td></tr><tr><td>HRG</td><td>☐</td></tr><tr><td>SNOMED</td><td>☐</td></tr><tr><td>Clinical coding / terming methodology used by clinical profession</td><td>☐</td></tr></table>
A8.3 **Identification Rules for Drugs:** How are drug costs captured?	**<u>Already specified in current NHS England Drugs List document</u>** If the drug has already been specified in the current NHS England Drug List please specify drug name and drug indication: Sapropterin for PKU is included on the NHS England Drug list as not routinely commissioned except for pregnant women Click here to enter text.
A8.4 **Identification Rules for Devices:** How are device costs captured?	**<u>Not applicable</u>** . Click here to enter text.
A8.5 **Identification Rules for Activity:** How are activity costs captured?	**<u>Already correctly captured by an existing specialised service line (NCBPS code within the PSS Tool</u>** Associated OP activity for paediatric patients will be captured by the IR NCBPS36Z Metabolic Disorders. Associated activity relating to adults will be paid by CCGs due to the lack of granularity of coding in the outpatient dataset. There is not anticipated to be any change in outpatient activity as

<table>
<tr><td></td><td>the drug will be supplied via homecare and patients will already be under the care of clinicians.</td></tr>
<tr><td colspan="2">A9 Monitoring</td></tr>
<tr><td>A9.1 Contracts
Specify any new or revised data flow or data collection requirements, needed for inclusion in the NHS Standard Contract Information Schedule.</td><td><u>None</u>
Please specify
Click here to enter text.</td></tr>
<tr><td>A9.2 Excluded Drugs and Devices (not covered by the Zero Cost Model)
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.</td><td>Select all that apply:
<table><tr><td>Drugs or Device MDS</td><td>☒</td></tr><tr><td>Blueteq</td><td>☒</td></tr><tr><td>Other prior approval</td><td>☐</td></tr></table>Please specify: Click here to enter text.</td></tr>
<tr><td>A9.3 Business intelligence
Is there potential for duplicate reporting?</td><td><u>No</u>
If yes, please specify mitigation:
Click here to enter text.</td></tr>
<tr><td>A9.4 Contract monitoring
Is this part of routine contract monitoring?</td><td><u>Yes</u>
If yes, please specify contract monitoring requirement:
Routine excluded drugs patient level MDS</td></tr>
<tr><td>A9.5 Dashboard reporting
Specify whether a dashboard exists for the proposed intervention?</td><td><u>No</u></td></tr>
</table>

	If yes, specify how routine performance monitoring data will be used for dashboard reporting. Click here to enter text. If no, will one be developed? This could be included in the Metabolic CRG Dashboard which already includes measures for PKU Click here to enter text.
A9.6 **NICE reporting** Are there any directly applicable NICE or equivalent quality standards which need to be monitored in association with the new policy?	**No** If yes, specify how performance monitoring data will be used for this purpose. Click here to enter text.
Section B - Service Impact	
B1 Service Organisation	
B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.)	There are c19 specialist metabolic centres. Paediatric clinics are commissioned and funded by NHS England and adult clinics are funded by CCGs (due to the lack of granularity of coding in outpatients). *Source: required*
B1.2 Will the proposition change the way the commissioned service is organised?	**No** Please specify: Click here to enter text. *Source: required*
B1.3 Will the proposition require a new approach to the organisation of care?	**No change to delivery of care** Please specify: Click here to enter text.

<table>
<tr><th colspan="2">B2 Geography & Access</th></tr>
<tr><td>B2.1 Where do current referrals come from?</td><td>Select all that apply:
<table><tr><td>GP</td><td>☐</td></tr><tr><td>Secondary care</td><td>☒</td></tr><tr><td>Tertiary care</td><td>☐</td></tr><tr><td>Other</td><td>☒</td></tr></table>Please specify:
New-born screening</td></tr>
<tr><td>B2.2 What impact will the new policy have on the sources of referral?</td><td><u>No impact</u>
Please specify:
Click here to enter text.</td></tr>
<tr><td>B2.3 Is the new policy likely to improve equity of access?</td><td><u>Increase</u>
Please specify:
Only pregnant women can access this drug routinely currently
Source: Equalities Impact Assessment</td></tr>
<tr><td>B2.4 Is the new policy likely to improve equality of access and/or outcomes?</td><td><u>Increase</u>
Please specify:
Only pregnant women can access this drug routinely currently, access to sapropterin, particularly for children will reduce brain damage caused by Phe levels
Source: Equalities Impact Assessment</td></tr>
</table>

B3 Implementation	
B3.1 Will commissioning or provider action be required before implementation of the proposition can occur?	**No action required** Please specify: Click here to enter text.
B3.2 **Time to implementation:** Is a lead-in time required prior to implementation?	**No - go to B3.4** If yes, specify the likely time to implementation: Enter text
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: Click here to enter text.
B3.4 Is a change in provider physical infrastructure required?	**No** Please specify: Click here to enter text.
B3.5 Is a change in provider staffing required?	**No** Please specify:
B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?	**No** Please specify: Click here to enter text.
B3.7 Are there changes in the support services that need to be in place?	**No** Please specify:

<table>
<tr><td></td><td>Click here to enter text.</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><u>No</u>
Please specify:
Click here to enter text.</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>Choose an item.
Please complete 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>7</td><td>7</td><td>C</td></tr>
<tr><td>Midlands & East</td><td>5</td><td>5</td><td>C</td></tr>
<tr><td>London</td><td>3</td><td>3</td><td>C</td></tr>
<tr><td>South</td><td>4</td><td>4</td><td>C</td></tr>
<tr><td>Total</td><td>19</td><td>19</td><td>C</td></tr>
</table>
Please specify:
Although NHS England is the commissioner for metabolic services, much of the activity relating to this specialty sits with CCG portfolios. There are also some shared care arrangements between providers currently. Some centres are managed through a tertiary centre and funded by CCGs. This drug is not suitable for shared care.</td></tr>
<tr><td>B3.10 Specify how revised provision will be secured by NHS England as the responsible commissioner.</td><td>Select all that apply:
<table>
<tr><td>Publication and notification of new policy</td><td>☒</td></tr>
<tr><td>Market intervention required</td><td>☐</td></tr>
</table></td></tr>
</table>

	Competitive selection process to secure increase or decrease provider configuration ☐ Price-based selection process to maximise cost effectiveness ☐ Any qualified provider ☐ National Commercial Agreements e.g. drugs, devices ☐ Procurement ☐ Other ☐ 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: This a high cost drug delivered from specialist centres which cross CCG/STP/ICS boundaries.
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.	Pack of 30 x 100mg tablets is £597.32 ex VAT. For children, average annual packs required is **37** (based on a dose of **10mg**/kg/day and an average weight of **30kg**) For adults, the average annual packs required is **114** (based on a dose of **12.5mg**/kg/day and an average weight of **75kg**)		
C1.3 **Device Costs**	N/A		

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.	
C1.4 **Activity Costs covered by National Tariffs** List all the HRG codes, HRG descriptions, national tariffs (excluding MFF), volume and other key costs (e.g. specialist top up %)	N/A
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.	Associated activity for paediatrics would be coded to treatment function code (TFC) 261 paediatric metabolic disease. This will either be paid as a block or at locally agreed prices. There is no equivalent code for adults and hence why activity is most likely to be paid by CCGs. There is no change anticipated to the number or cost of outpatient activity.
C1.6 **Other Activity Costs not covered by National or Local Tariff** Include descriptions and estimates of all key costs.	NA
C1.7 Are there any prior approval mechanisms required either during implementation or permanently?	**Yes** Please specify: Click here to enter text.
C2 Average Cost per Patient	

<table>
<tr><td>C2.1 What is the estimated cost per patient to NHS England, in years 1-5, including follow-up where required?

Are there any changes expected in year 6-10 which would impact the model?</td><td><table><tr><td></td><td>Adults</td><td>Paediatric</td></tr><tr><td>YR1</td><td>£52.1k</td><td>£17.3k</td></tr><tr><td>YR2</td><td>£68.5k</td><td>£22.1k</td></tr><tr><td>YR3</td><td>£68.5k</td><td>£22.1k</td></tr><tr><td>YR4</td><td>£68.5k</td><td>£22.1k</td></tr><tr><td>YR5</td><td>£68.5k</td><td>£22.1k</td></tr></table>
This is the impact of 1 patient starting treatment on day 1 (assumed to be July 2020) and continuing until the end of year 5 at list price.

No.</td></tr>
<tr><td colspan="2">C3 Overall Cost Impact of this Policy to NHS England</td></tr>
<tr><td>C3.1 Specify the budget impact of the proposal on NHS England in relation to the relevant pathway.</td><td><u>Cost pressure</u> (At list price)

<table><tr><td>Year 1</td><td>£6,501.0k</td></tr><tr><td>Year 2</td><td>£14,866.2k</td></tr><tr><td>Year 5</td><td>£17,709.9k</td></tr></table></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>N/A</td></tr>
</table>

<table>
<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>N/A</td></tr>
<tr><td colspan="2">C4 Overall cost impact of this policy 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 saving</u>
CCGs fund the synthetic protein supplements that are prescribed by GPs as part of the PKU diet. The cost per patient varies but is in the range of £12.6k to £16.0k per annum for adults and £10.8k to £11.1k for paediatrics. It is anticipated that there may be around a 50% reduction in prescribing for those patients taking Sapropterin. If this was realised, the CCG saving would be:
<table><tr><td>Year 1</td><td>£851.9k</td></tr><tr><td>Year 2</td><td>£2,189.7k</td></tr><tr><td>Year 5</td><td>£2,644.1k</td></tr></table>
It is also likely there would be a small reduction in the number of specialist dietitian and psychologist appointments (c7-10% of patients). However as these tend to be paid on a block base, the saving is difficult to quantify or realise.
Budget impact for providers:
<u>No impact on providers</u>
Please specify:</td></tr>
</table>

<table>
<tr><td>C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.</td><td><u>Cost pressure</u>
Please specify:
<table><tr><td>Year 1</td><td>£ 5,649.1k</td></tr><tr><td>Year 2</td><td>£12,676.5k</td></tr><tr><td>Year 5</td><td>£15,065.8k</td></tr></table>
Click here to enter text.</td></tr>
<tr><td>C4.3 Where the budget impact is unknown set out the reasons why this cannot be measured</td><td>Click here to enter text.</td></tr>
<tr><td>C4.4 Are there likely to be any costs or savings for non-NHS commissioners and/or public sector funders?</td><td><u>No</u>
Please specify:
There are likely to be further system wide savings in social care and other public funded bodies due to improvements in behavioural type problems.</td></tr>
<tr><td colspan="2">C5 Funding</td></tr>
<tr><td>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.</td><td>CPAG Prioritisation</td></tr>
<tr><td colspan="2">C6 Financial Risks Associated with Implementing this Policy</td></tr>
<tr><td>C6.1 What are the material financial risks to implementing this policy?</td><td>Not applicable</td></tr>
</table>

<table>
<tr><td>C6.2 How can these risks be mitigated?</td><td></td></tr>
<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>Click here to enter text.</td></tr>
<tr><td>C6.4 What scenario has been approved and why?</td><td>Click here to enter text.</td></tr>
<tr><td colspan="2">C7 Value for Money</td></tr>
<tr><td>C7.1 What published evidence is available that the treatment is cost effective as evidenced in the evidence review?</td><td><u>There is no published evidence of cost-effectiveness</u>
Please specify:
Click here to enter text.</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 treatment is equivalent cost compared to current/comparator treatment</td><td>☐</td></tr>
<tr><td>Available pricing data suggests the treatment is lower cost compared to current/comparator treatment</td><td>☐</td></tr>
<tr><td>Available clinical practice data suggests the new treatment 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>
</table></td></tr>
</table>

	The data does not support a high level of certainty about the impact on value ☐ Please specify: Click here to enter text.
C8 Cost Profile	
C8.1 Are there non-recurrent capital or revenue costs associated with this policy?	**No** If yes, specify type and range: Click here to enter text.
C8.2 If yes, confirm the source of funds to meet these costs.	Click here to enter text.