Integrated Impact Assessment Report for Service Specifications

Policy Reference Number	A14/S(HSS)/c		
Policy Title	Primary Ciliary Dyskinesia management service (adults)		
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Please also complete sections K, L and M on the CPAG finance template

Section A - Activity Impact

Theme	**Questions**	**Comments** (Include source of information and details of assumptions made and any issues with the data)
K1 Current Patient Population & Demography / Growth	A1.1 What is the prevalence of the disease/condition?	A1.1 Between 1:26000 - 1:40000
	A1.2 What is the number of patients eligible for this treatment under currently routinely commissioned care arrangements?	A1.2 Anticipated national caseload is 350 patients with an initial annual growth of 40/year to a realistic plateau of 600-700 patients.
	A1.3 What age group is the treatment indicated for?	A1.3 Adults, a service for children is already commissioned as a highly specialised service.
	A1.4 Describe the age distribution of the patient population taking up treatment?	A1.4 All ages. A recent audit at the Royal Brompton Hospital found the median age was 35 with a range of 19-75 (IQR 26-47).An estimated 350 patients are identified currently as PCD patients. Initial annual growth of 40 patients /year to a maximum of c600-700 patients
	A1.5 What is the current activity associated with currently routinely commissioned care for this	A1.5 Yr 2 - 390 Yr 5 - 510

	group?	Yr 10 - 700
	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 At the moment the patients aren’t managed in an expert centre, though the current cohort of patients and increasing numbers of patients will be managed in the system regardless of the agreement of expert centres to manage their care.
	A1.7 What is the associated projected growth in activity (prior to applying the new policy) in 2,5 and 10 years	A1.7 The changes will centralise the management of the cohort of patients into expert centres, the activity in these centres will increase as described. The incidence of the condition is not significantly changed.
	A1.8 How is the population currently distributed geographically?	A1.8 Expected to be broadly evenly distributed with some hotspots generated by particular family groups.
K2 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 There is currently no specialised management of this condition. This service is currently commissioned by CCGs.
	A2.3 Please describe any factors likely to affect growth in the patient population for this intervention (e.g. increased disease prevalence, increased survival)	A2.2 Appropriate management of this patient group has been demonstrated to reduce disease progression and should therefore reduce premature death and enhance the quality of life for patients with PCD.
	A2.3 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	A2.4 Year 2 +40 Year 5 +160 Year 10 +350

	and 10?	
K3 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 It is difficult to be precise but it is estimated that circa 250 PCD patients are currently receiving treatment in one of the four expert centres and a further 100 patients are receiving treatment in a number of other providers. A3.2 Each patient will have an annual review at the centre. A 1/3 of patients will be seen 2x year and 1/3 of patients quarterly. There will also be a small amount of inpatient activity for patient, though length of stay can be quite long. A3.3 PSSAG agreed to transfer the commissioning responsibility for this service from CCGs to NHS England from April 2016. Hence NHS England has the responsibility to code and fund activity for adult PCD patients from 2016.
K4 Existing Patient Pathway	A4.1 If there is a relevant currently routinely commissioned treatment, what is the 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?	A4.1 This service is not currently commissioned by NHS England. There are approximately 250 patients presently cared for in the proposed PCD management centres, with most likely 100 cared for elsewhere in disparate clinics and centres. A4.2 Not currently specialised A4.3 Not currently specialised
K5 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	A5.1Not currently specialised. A5.2About 20-40 new adult patients are diagnosed with confirmed or probable (with indeterminate diagnostic results) PCD each year, with 20-40

	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.	transitioning from the HSS paediatric management services.
K6 New Patient Pathway	A6.1 Describe or include a figure to outline associated activity with the patient pathway for the proposed new policy. 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.	A6.1 Maximum number of patients 600-700. A6.2 All patients to have an annual review 1/3 of patients to have an additional 6 month outpatient appointment and 1/3 of patients seen quarterly. 600-700 outpatients Patients would only leave the service at death. In an audit at Royal Brompton, 4.6% of patients died over a median 7 year follow up.
K7 Treatment Setting	A7.1How is this treatment delivered to the patient? 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/Daycase/Outpatient A7.2 A degree of centralisation of the service will result in a need for an increase in capacity in the highly specialised services.
K8 Coding	A8.1 In which datasets (e.g. SUS/central data collections etc.) will activity related to the new patient pathway be recorded? A8.2 How will this activity related to the new patient pathway be identified?(e.g. ICD10 codes/procedure codes)	A8.1 SUS data flows A8.2 The activity of patients would be captured by the ICD10 code for PCD Q34.8.
K9 Monitoring	A9.1 Do any new or revised requirements need to be included in the NHS Standard Contract Information Schedule? If so, these must be communicated to CTownley@nhs.net, ideally by end of October to inform following year's contract	A9.1 Likely not applicable but could depend on currency adopted for service.

	A9.2 If this treatment is a drug, what pharmacy monitoring is required? A9.3 What analytical information /monitoring/ reporting is required? A9.4 What contract monitoring is required by supplier managers? What changes need to be in place? A9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring? A9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy? 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*	A9.2 Not applicable. A9.3 Monitoring via the established processes for Highly Specialised Services via the HSS Informatics lead. A9.4 Inclusion in NHS Standard Contract Information Schedule and service lines monitored. Data will be provided to supplier managers via the HSS informatics lead. A9.5 Monitoring of this service is not included in the specialised respiratory dashboard. Monitoring of the agreed outcomes will be vis the HSS team. A9.6 No 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)
L1 Service Organisation	B1.1 How is this service currently organised (i.e. tertiary centres, networked provision)	B1.1 There are currently a small number of centres with expertise in managing this condition, however many patients are seen in disparate clinics without specialist care. A PCD paediatric service is commissioned by NHS England. At present there is no continuity of specialised care into adulthood. This leaves a significant void of specialist care at transition to adulthood, a vulnerable period for patients.

	B1.2 How will the proposed policy change the way the commissioned service is organised?	B1.2 The service will provide continuity for the paediatric population. The service will ensure that all patients, wherever they live, have access to and are managed according to agreed PCD Standards of Care.
L2 Geography & Access	B2.1 Where do current referrals come from?	B2.1 Referrals originate from the paediatric PCD services, another adult PCD service if a patient is transferring geographical location, primary care physicians for adult patients with known PCD, and secondary care (mainly but not exclusively respiratory and ENT services) for adult patients with known or suspected PCD.
	B2.2 Will the new policy change / restrict / expand the sources of referral?	B2.2 The policy should expand the sources of referral with more patients being referred into the centre for expert management.
	B2.3 Is the new policy likely to improve equity of access?	B2.3 Yes that is the intention of the proposed service.
	B2.4 Is the new policy likely to improve equality of access / outcomes?	B2.4 Yes and systems will be put in place to measure both equity of access and outcomes for patients.
L3 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 Some expert provision has been identified and of course there is currently a number of centres managing a cohort of these patients. A certain level of service could be provided immediately with subsequent expansion of multidisciplinary input over time.
	B3.2 Is there a change in provider physical infrastructure required?	B3.2 No
	B3.3 Is there a change in provider staffing required?	B3.3 Yes the PCD MDT would consist of a PCD specialist consultant, physiotherapist, nurse specialist and ENT specialist
	B3.4 Are there new clinical dependency / adjacency requirements that would need to be in place?	B3.4 The entire structure of the services would need to be established as well as outreach provision and home intravenous antibiotic service.

	B3.5 Are there changes in the support services that need to be in place?	B3.5 There will be some, access to diagnostic testing will be needed.
	B3.6 Is there a change in provider / inter-provider governance required? (e.g. ODN arrangements / prime contractor)	B3.6 Unlikely
	B3.7 Is there likely to be either an increase or decrease in the number of commissioned providers?	B3.7 This service is not currently commissioned by NHS England.
	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 To be determined by RDAG but a competitive selection process will be required with due regard to numbers of centres needed to maintain expertise, a reasonable geographic spread plus links to the highly specialised paediatric services.
L4 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, the intention is to commission the services as a highly specialised service.
Section C- Finance Impact		
Theme	**Questions**	**Comments** (Include source of information and details of assumptions made and any issues with the data)
M1 Tariff	C1.1 Is this treatment paid under a national prices*, and if so which?	C1.1 There would be an option to adopt national prices for some elements of the service, e.g. multidisciplinary outpatients, but query whether tariffs adequately reflect the costs.
	C1.2 Is this treatment excluded from national prices?	C1.2 High cost drug exclusions will be charged outside of tariff.
	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 This is a new patient management service, so there are options for currencies and pricing. Under a competitive selection process, providers could be invited to submit proposals for innovative pricing approaches, which could inform future tariff development for this service.

	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 – financial modelling has been based on provider costs and not assumed prices.
	C1.5 is VAT payable (Y/N) and if so has it been included in the costings?	C1.5 Assumed excluded for homecare delivery drugs
	C1.6 Do you envisage a prior approval / funding authorisation being required to support implementation of the new policy?	C1.6 No
M2 Average Cost per Patient	C2.1 What is the revenue cost per patient in year 1?	C2.1 Calculated at £8,721 incl. pass through drugs costs at £2,934.
	C2.2 What is the revenue cost per patient in future years (including follow up)?	C2.2 Year 2 £8,324, Year 5 £8,036, Year 10 £7,579 reflecting services working to capacity.
M3 Overall Cost Impact of this Policy to NHS England	C3.1 Indicate whether this is cost saving, neutral, or cost pressure to NHS England?	C3.1 Cost pressure to NHS England of £3.1m Yr 1 (£3.3m Yr 2, £4.1m Yr 5). Current care is funded from CCG resources estimated at around £2m for baseline patient cohort.
	C3.2 Where this has not been identified, set out the reasons why this cannot be measured?	C3.2 It is anticipated that better management of these patients will have a positive impact on disease progression and morbidity, with reduced hospitalisations and need for advanced respiratory support. However, it has not been possible to evaluate the savings associated with these benefits.
M4 Overall cost impact of this policy to the NHS as a whole	C4.1 Indicate whether this is cost saving, neutral, or cost saving for other parts of the NHS (e.g. providers, CCGs)	C4.1 PSSAG agreed to transfer the commissioning responsibility for this service from CCGs to NHS England from April 2016. On the assumption that it will be difficult to accurately identify activity and current costs being funded by CCGs it is unlikely that baseline transfers will be actionable, so there will be a saving to CCGs when commissioning is transferred.

	C4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as 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?	C4.2 Net cost pressure for the new service, estimated at £1m Yr 1, £1.2m Yr 2, £2.1m Yr 5 C4.3 N/A C4.4 N/A
M5 Funding	C5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified	C5.1 From within specialised commissioning recurrent allocation envelope, note unlikely to secure allocation transfers from CCGs.
M6 Financial Risks Associated with Implementing this Policy	C6.1 What are the material financial risks to implementing this policy? C6.2 Can these be mitigated, if so how? C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios	C6.1 Risks around cost estimates used, although these have been developed in collaboration with provider that has expertise in managing patients with this condition. C6.2 Mitigation can be through application of pricing conditions included in the competitive selection process. C6.3 No other scenarios have been tested. Costing is based on anticipated service staffing model.
M7 Value for Money	C7.1 What evidence is available that the treatment is cost effective?	C7.1 The intention is to reduce the morbidity and mortality related to PCD, as well as the economic burden, associated with late diagnosis and poorly managed disease. Such specialised management is likely to be cost effective by reducing the overall financial burden of poorly managed disease to the NHS. This condition, when aggressively targeted and managed can largely be dealt with in out-patients, significantly reducing expensive in-patient stays, staffing needs per patient, time off work and the less well defined socioeconomic costs of chronic ill health with disability.

	C7.2 What issues or risks are associated with this assessment?	There is some published work on the cost effectiveness of diagnostic models for PCD. C7.2 N/A
M8 Cost Profile	C8.1 Are there non-recurrent capital or revenue costs associated with this policy? C8.2 If so, confirm the source of funds to meet these costs.	C8.1 Immaterial non-recurrent revenue set-up costs included in year 1 analysis above (£6k). C8.2 Specialised commissioning allocation.