

## Integrated Impact Assessment Report for Clinical Service Specifications

Reference Nun	nber E13/S(HSS)/a	E13/S(HSS)/a		
Title	Revised Specification for G	Revised Specification for Gender Identity Development Service for Children and Adolescents		
Accountable Commissioner	Bernie Stocks	Bernie Stocks Clinical Dr Edmund Jessop		
Finance Lead	Shekh Motin	Analytical Lead	Charlotte Ellis, Peter Street	
	·	Astivity Inno	-1	
		Activity Impa	ct	
Theme	Questions	<b>Comments</b> (Include source of information and details of assumptions made and any issues with the data)		
Note to the real	ader:			
Note 1: The activity and additional cost impact of the revised specification for this service is related to bringing forward				
the time for adolescents to access cross sex hormones from 16 years to 15 years and 10 months - but only for those				
clients who have been assessed as a) having the competency and autonomy to consent to the treatment and b) which				
			posal is to provide legitimate flexibility on a case by	
case basis around the timing of clinic appointments around the client's 16th birthday as the current system does not				

	Illow for some individuals to be seen until a number of months after their 16th birthday. Note 2: The provider of the service has made a commitment to absorb the additional costs of bringing forward the age		
		5 years and 10 months as indicated within this document within the	
	sation monies.	NHS England is zero impact and no monies are required from	
K1 Current Patient Population & Demography / Growth	K 1.1 What is the prevalence of the disease/condition?	K1.1 Formal epidemiological studies on Gender Dysphoria (GD) among adolescents of 15 years or older and adults are usually based on the number of people who have been treated at gender identity clinics. Estimates of the prevalence of GD range from a lower estimate of 1:2000 (or about 0.05%) in the Netherlands and Belgium (Conway 2008) to 1.2% in New Zealand (Clark et al 2014). These numbers are based on those who identify as transgender.	
	K1.2 What is the number of patients eligible for this treatment under currently routinely commissioned care arrangements?	In England, the number of referrals to the service is increasing, with some 1400 new referrals projected for 15/16. K1.2 The current clinical protocol in England is that the service can prescribe cross-sex hormones to adolescents of 16 years and above who have been assessed as having persistent GD* and have been receiving hormone blockers for a minimum of one year following assessment in the services' Paediatric Endocrine Liaison team via the Early Intervention Clinic. The cross sex hormones are prescribed in addition to the hormone blockers and are introduced on a phased way to achieve the correct level. * To be in scope for cross sex hormones from 16 years plus or minus two months, clients need to have: a) been seen in the service's Paediatric Endocrine Liaison team's Early	

	b) received hormone blockers for one year or more and
	c) been assessed as having persistent GD and
	d) have expressed the wish to receive cross sex hormones, with the agreement of their family or carers and
	e) had further assessment and are considered to meet the criteria to receive cross sex hormones.
	f) been assessed as having the competency and autonomy to consent to the treatment.
	This impact of this specification is to bring forward the prescribing of cross sex hormones to a limited number of adolescents up to two months before their 16th birthday each year. This will impact on 15 <sup>*</sup> clients in year one (2016/17) with a predicted average annual growth rate of up to 20% over 10 years, (including average 10% referral growth rate plus separate age profile change). This will provide legitimate flexibility on a case by case basis around the timing of clinic appointments around the client's 16th birthday as the current system does not allow for some individuals to be seen until a number of months after their 16th birthday.
JBLIC	* 15 patients is the current number of eligible patients in the early intervention group who would be eligible for cross sex hormones by the age of 15 years and 10 months in 16/17. This would be the maximum number as not all patients may wish to proceed with this treatment.
K1.3 What age group is the treatment indicated for?	K1.3 Adolescent clients two months before their 16th birthday who have had a full assessment as described in K1.2.
K1.4 Describe the age distribution of	K1.4 Clients aged between a)15 years and 10 months to b) 16th

the patient population taking up treatment?	birthday
K1.5 What is the current activity associated with currently routinely commissioned care for this group?	K1.5 The current activity in scope is for those clients who have attended the Paediatric Endocrine Liaison team's Early Intervention Clinic where they have received hormone blockers and then gone on to receive cross sex hormones after their 16 <sup>th</sup> birthday; 17 patients in 15/16.
K1.6 What is the projected growth of the disease/condition prevalence (print to applying the new policy) in 2, 5, an 10 years	
	Only 3-5% of total referrals to the GIDS service are in scope for cross sex hormones per annum.
PUBL	Current estimates are that the prevalence of GD may be presumed to be static, although presentation rates are increasing due to increased social acceptance, social and media interest, greater access to information via the internet amongst other factors- which have resulted in 50% increase in new referrals year on year since 2009, although this has risen to 100% in 15/16. (New referrals in 2014/15 were 697 and the projected outturn of new referrals for 15/16 is 1400).
K1.7 What is the associated projected growth in activity (prior to applying the new policy) in 2,5 and 10 years	

	There are 15 pa	atients who are in sc	ope for cross sex hormon	es in
	16/17 having be	een to the Early Inter	vention clinic – the number	er
	predicted over	the next 10 years if t	he policy is not implement	ted is:
		Growth rate	Number in scope for	
		(assume average	cross sex hormones at	
		rate of 20% per	16 years	
	2016/17	annum over 10 years – this is	15	
	2017/18	based on a) 15%	18	
	2020/21	growth in referrals and b) a 5% age	31	
	2025/26	profile change,	77	
		although it is		
		assumed that it		
		will level out over 10 years)		
(				
			in K1.6, demand for this s	
. ( )	<b>.</b>		ediatric services. Growth gh the figure is likely to be	
	-		average of 20% per annu	
			n addition, there could be	
			on the experience of the l	
			er people who enter the s	
		<b>J</b>	tervention Clinic would inc I, and the number referred	
		•	al profile takes place in Er	
	, ,		e eligible for cross sex hor	•
			se year on year rather that	
	decrease.			

	K1.8 How is the population currently distributed geographically?	K1.8 Currently more referrals are received from the Midlands and the South*, which are broadly in line with the population base, but this is expected to even out and become more aligned to the population base over time.
		*The service's referral data for the English population (95% of total) between 2009 to 2015 shows that 35% were from the South, 24% were from the Midlands, 23% were from the North and 13% were from London.
K2 Future Patient Population & Demography	K2.1 Does the new service specification : 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?	K2.1 The specification expands current clinical practice by two months to 15 years and 10 months as compared to from the 16 <sup>th</sup> birthday as now, which will provide legitimate flexibility on a case by case basis around the timing of clinic appointments around the client's 16th birthday. The concern is that the current system does not allow for some individuals to be seen until after their 16th birthday.
	K2.2 Please describe any factors likely to affect growth in the patient population for this intervention (e.g. increased disease prevalence, increased survival).	K2.2 Presentation rates are increasing due to increased social acceptance, social and media interest, greater access to information via the internet amongst other factors- which have resulted in 50% increase in new referrals year on year since 2009, although this has risen to 100% in 15/16. (New referrals in 2014/15 were 697 and the projected outturn of new referrals for 15/16 is 1400). Any change in the number of children with features of Autistic Spectrum Disorder (ASD) or who have a diagnosis of ASD or Asperger Syndrome. As a significant proportion of clients have these conditions.
	K 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	K2.3 Presentations are assumed to be related to population size rather than any geographic hot spots per se.

	details K2.4 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?	service now wh	ow, plus growth – it	e (the same r	number of people as are
			Growth rate (assume average rate of 20% per annum over 10 years – this is based on a) 15%	Number in scope for cross sex hormones at 15 years and 10 months	Total number of additional appointments needed (1 extra appointments per patient)
		1 year (2016/17) 2 years (2017/18)	growth in referrals and b) a 5% age profile change, although it is assumed that it	15 18	15 18
		5 years (2020/21)	will level out over 10 years)	31	31
	BY	10 years (2025/26)		77	77
K3 Activity	K3.1 What is the current annual activity for the target population covered under the new service specification Please provide details in accompanying excel sheet	In 2016/17, refe which up to 15		o increase b to be in sco	5/16 is 1400 patients. y some 20% to 1560, of pe for cross sex

	K3.2 What will be the new activity should the new service specification be implemented in the target population? Please provide details in accompanying excel sheet	K3.2 - see K2.4
	K3.3 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	K3.3 Continue with psychological counselling or hormone blockers alone until the 16 <sup>th</sup> birthday.
K4 Existing Patient Pathway	K4.1 If there is a relevant currently routinely commissioned treatment, what is the current patient pathway? Describe or include a figure to outline associated activity.	K4.1 No formalised commissioned activity under the age of 16 for the prescribing of cross sex hormones.
	K4.2 What are the current treatment access criteria?	<ul> <li>K4.2</li> <li>K4.2.1 Criteria for acceptance into the general GIDS service:</li> <li>Referrals will be accepted from a range of professionals including CAMHS professionals, GPs, secondary care clinicians including paediatricians and gynaecologists, schools and colleges of further education.</li> <li>Referrals will be accepted if there is evidence of features consistent</li> </ul>
	KOR I	<ul> <li>with a diagnosis of GD and identified risk is being managed locally;</li> <li>If, after assessment, it is apparent that the young person does not fulfil the criteria for a diagnosis of GD, or it is concluded that there are no issues with gender identity development, the case will be closed and the young person referred back to their GP or other referring healthcare</li> </ul>

	professional, with advice regarding appropriate support.
	K4.2.2 Criteria for referral to the Paediatric Endocrine Liaison Team for hormone blockers in the early stages of puberty and/or under the age of fifteen.
	• The adolescent has been presenting with long term and persistent GD and the intensity and distress has increased with puberty;
	• The adolescent presents as relatively stable psychologically as evaluated through clinical observation and questionnaires,
	<ul> <li>There is support from the family or carers,</li> </ul>
	<ul> <li>In some cases, the referral to the paediatric clinic is made for the purpose of physical assessment e.g. to exclude a disorder of sex development or other endocrine conditions,</li> </ul>
	• To provide information about physical development in order to allay some anxieties in the adolescent patient and the family.
	• Young people under 16 should be assessed able to give informed consent and have the appropriate autonomy to make decisions
	K4.2.3 Criteria for prescribing cross-sex hormones
BHO	There is a diagnostic template which is used to assess the readiness for intervention with cross-sex hormones, which has been agreed in conjunction with the NHS England adult gender identity service teams and includes:
	diagnosis of GD
	• the client is aged 16 years plus or minus one or two months depending on the date of the endocrine clinic follow up appointment
	the client is able to give informed consent
	<ul> <li>impact on fertility has been discussed and the implications are understood</li> </ul>

		<ul> <li>some evidence of presentation coherent with gender identity, for example deed poll name change</li> </ul>
		<ul> <li>the client is engaged in or taking steps to secure, meaningful activity such as education or employment, accepting that societal limitations may affect this</li> </ul>
		<ul> <li>there is support for the client from the family or carers or social support if the client is a 'Looked After Child', and the Local Authority been consulted</li> </ul>
		<ul> <li>the client is in good physical health</li> </ul>
		<ul> <li>associated difficulties such as self-harm are not escalating or are being actively monitored and managed by local healthcare professionals. This will be assessed on a case by case basis</li> </ul>
		<ul> <li>the client has not smoked for a minimum of three months</li> </ul>
		<ul> <li>the client is therapeutically engaged with the service</li> </ul>
		<ul> <li>at least two clinicians agree on the suitability of the client receiving cross-sex hormones</li> </ul>
	K4.3 What are the current treatment stopping points?	K4.3 Stopping points:
		<ol> <li>If there are any concerns about the client's physical health such as low bone density</li> </ol>
		2. If the family /young person does not attend regular follow ups at the Paediatric Endocrine Liaison Clinic and/or the GIDS general clinics as agreed in their care plan.
	LORY	3. If the client is having a significant psychotic or other significant mental health disorder that is not adequately controlled as this may reduce their ability to manage the emotional issues that may arise from the changes in hormone levels from the hormone treatments and may impact on their capacity to consent.

		<ul><li>4. If there are physical contraindications that require further investigation.</li><li>5. If the client decides to cease treatment for any reason</li></ul>
K5 Comparator (next best alternative treatment) Patient	K5.1 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.	K5.1 Continue with psychological counselling or hormone blockers alone until the 16 <sup>th</sup> birthday.
Pathway	K5.2 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.	K5.2 For the stopping points described in K4.3, 0.5% of 40 people are likely to stop cross sex hormone treatment in any one year, which equates to one person every two years.
K6 New Patient Pathway	<ul> <li>K6.1 Describe or include a figure to outline associated activity with the patient pathway for the proposed new service specification</li> <li>K6.2 Where there are different stopping points on the pathway please indicate how many patients out of the number starting the pathway would be</li> </ul>	K6.1 Number in scope for cross sex hormones at 15 years and 10 months See K2.4 K6.2 Not applicable

	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.	A ONIX
K7 Treatment Setting	K7.1How is this treatment delivered to the patient? K7.2 Is there likely to be a change in delivery setting or capacity requirements, if so what? <i>e.g. service capacity</i>	K7.1 Acute Trust: Inpatient No, Outpatient Yes – GIDS Paediatric Endocrine Liaison Clinic activity Mental Health Provider: Inpatient No, Outpatient Yes Community setting: No Homecare delivery: No K7.2 No expected change in delivery setting
K8 Coding	<ul> <li>K8.1 In which datasets (e.g. SUS/central data collections etc.) will activity related to the new patient pathway be recorded?</li> <li>K8.2 How will this activity related to the new patient pathway be identified?(e.g. ICD10 codes/procedure codes)</li> </ul>	K8.1 bespoke report. K8.2 procedure codes

K9	K9.1 Do any new or revised	K9.1 No
Monitoring	requirements need to be included in the NHS Standard Contract Information Schedule? If so, these must be communicated to	
	<u>CTownley@nhs.net</u> , ideally by end of October to inform following year's contract	
	K9.2 If this treatment is a drug, what pharmacy monitoring is required?	K9.2 Standard monitoring via senior pharmacist as now
	K9.3 What analytical information /monitoring/ reporting is required?	K9.3 As now
	K9.4 What contract monitoring is required by supplier managers? What changes need to be in place?	K9.4 As now, no change
	K9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring?	K9.5 No
	K9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy?	K9.6 No
	K9.7 Do you anticipate using Blueteq	K9.7 Not at present

ac	r other equivalent system to guide ccess to treatment? If so, please utline. See also linked question in 11 below		
		Service Impact	
Theme	Questions	<b>Comments</b> (Include source of information and details of assumptions made and any issues with the data)	
L1 Service L1.1 How is this service currently organised (i.e. tertia centres, networked provision)		L1.1 There is a single national designated provider which subcontracts with an acute provider for the Paediatric Endocrine Liaison Clinics	
	L1.2 How will the proposed service specification change the way the commissioned service is organised?	L1.2 There will be no change to the current arrangements	
L2 Geography & Access	L2.1 Where do current referrals come from?	L2.1 GP's, secondary care paediatric consultants	
	L2.2 Will the new service specification change / restrict / expand the sources of referral?	L2.2 Referrals should still come from the same source.	
	L2.3 Is the new service specification likely to improve equity of access?	L2.3 Yes	
	L2.4 Is the new service specification likely to improve	L2.4 Yes it will reduce the wait experienced by some clients who are competent to consent to treatment.	

	equality of access / outcomes?	
L3 Implementation	L3.1 Is there a lead in time required prior to implementation and if so when could implementation be achieved if the service specification is agreed?	L3.1 Yes, this will be phased in over first six months in 2016/17
	L3.2 Is there a change in provider physical infrastructure required?	L3.2 No
	L3.3 Is there a change in provider staffing required?	L3.3 Yes. Increase in the clinics and clinical nurse specialist time needed.
	L3.4 Are there new clinical dependency / adjacency requirements that would need to be in place?	L3.4 No.
	L3.5 Are there changes in the support services that need to be in place?	L3.5 No
	L3.6 ls there a change in provider / inter-provider governance required? (e.g. ODN arrangements / prime contractor)	L3.6 No

	<ul> <li>L3.7 Is there likely to be either an increase or decrease in the number of commissioned providers?</li> <li>L3.8 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)</li> </ul>	L3.7 No change. L3.8. Given the commitment by the single national provider to absorb the costs from 16/17 and beyond as an efficiency improvement, the NHS England contract with the single provider of the service (which sub-contracts with an acute provider for the assessment of clients for the prescribing of cross sex hormones) will not need to increase to reflect this service change.	
L4 Collaborative Commissioning	L4.1 Is this service currently subject to or planned for collaborative commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements)?	L4.1 No	
Finance Impact			
Theme	Questions		<b>Comments</b> (Include source of information and details of assumptions made and any issues with the data)
M1 Tariff	M1.1 Is this treatment paid under prices*, and if so which?	r a national	M1.1 There is a block contract for the GIDS service, although there is separate funding stream within the contact for an outpatient appointment and assessment in the Paediatric Endocrine Liaison

		clinic at a cost of £472 per attendance.
	M1.2 Is this treatment excluded from national prices?	M1.2 Yes it is excluded
	M1.3 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?	M1.3 Covered in the block contract although the drug costs are only for the first two months it is then pricked up by those GPs willing to prescribe. Where this isn't the case, NHS England will pay for the costs for these patients.
	M1.4 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	M1.4 Not applicable
	M1.5 is VAT payable (Y/N) and if so has it been included in the costings?	M1.5 No
	M1.6 Do you envisage a prior approval / funding authorisation being required to support implementation of the new service specification?	M1.6 No
M2 Average Cost per Patient	M2.1 What is the revenue cost per patient in year 1?	M2.1 As the provider is to absorb the costs, there is no cost to NHS England, the cost to the provider will be (for up to 15 extra patients in year 1 2016/17), there will be a cost of an extra £472 per patient for each of one extra clinic attendance = $(15x1) \times £472 = £7,080$ in 2016/17

	M2.2 What is the revenue cost per patient in future years (including follow up)?	as now but th	nere may be a	s seen, the co growth in the ach year as fo	number of
		Year of impact	Number in scope for cross sex hormones at 15 years and 10 months	Cost per annum at £472 for 1 extra appointme nt per client £	
		1 year (2016/17)	15	£7,080	
	SU	2 years (2017/18	18 extra versus baseline	£8,496	
	e cor	5 years ( 2020/21)	31 extra versus baseline	£14,632	
		10 years (2025/26)	77extra versus baseline	£36,344	
M3 Overall Cost Impact of this Policy to NHS England	M3.1 Indicate whether this is cost saving, neutral, or cost pressure to NHS England?	M3.1 Neutral as the provider is to absorb the cost as an efficiency measure.		o the cost	
	M3.2 Where this has not been identified, set out the reasons why this cannot be measured?	M3.2 It can b	e measured.		
M4 Overall cost	M4.1 Indicate whether this is cost saving, neutral,	M4.1 This wo	ould be cost n	eutral to NHS	England.

impact of this policy to the NHS as a whole	or cost saving for other parts of the NHS (e.g. providers, CCGs)	, L
	M4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as a whole?	M4.2. cost pressure – but Provider to absorb as an efficiency offer.
	M4.3 Where this has not been identified, set out the reasons why this cannot be measured?	M4.3 It can be measured
	M4.4 Are there likely to be any costs or savings for non NHS commissioners / public sector funders?	M4.4 GPs/primary care will incur the cost for up to two additional months treatment per client, but for those few GPs affected (x only 15 nationally in 16/17), they are likely to have only one patient each. The cost to GPs* is likely to be up to £13 per patient as a one off cost for testosterone ( for female to male clients) and up to £7 per patient as a one off cost for oestrogen (for male to female clients).
		*Testosterone (female to male clients) - Estradiol valerate tablets assuming 4mg daily =£80/year approx
		Oestrogen (male to female) - Sustanon 250mg x three weekly = $\pounds$ 43/year.
M5 Funding	M5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified	None for NHS England
M6 Financial Risks Associated with	M6.1 What are the material financial risks to implementing this service specification ?	No material financial impact is expected

Implementing this Policy	M6.2 Can these be mitigated, if so how?	n/a
	M6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios.	n/a
M7 Value for Money	M7 M7.2 What issues or risks are associated with this	M7.2 none
	assessment?	
M8 Cost Profile	M8.1 Are there non-recurrent capital or revenue costs associated with this service specification?	None for NHS England.
	M8.2 If so, confirm the source of funds to meet these costs.	

these costs.