Integrated Impact Assessment Report for Clinical Commissioning Policies

Policy Reference Number	E03X16/01		
Policy Title	**Prescribing of Cross-Sex Hormones as part of the Gender Identity Development Service for Children and Adolescents**		
Accountable Commissioner	Bernie Stocks	**Clinical Lead**	Dr Edmund Jessop
Finance Lead	Shekh Motin	**Analytical Lead**	Charlotte Ellis, Peter Street
Please also complete sections K, L and M on the CPAG finance template			

Section K - Activity Impact

Notes to the reader

Note 1: There is no financial impact for the policy proposition as it is a Not Routinely Commissioned (NRC) policy, however the costs have been included to indicate what the costs would be if it were to be approved in the future – which would see the age of access change from 16 to 15 - which would see up to 40 patients in scope in year 1.

Note 2: Referrals to the GIDS service are usually made before puberty or after puberty starts:

1) **Pre-puberty e.g at age 10-12 and following assessment in the general GIDS clinic, those clients assessed as having persistent Gender dysphoria may be referred to the Paediatric Endocrine Liaison Team's *Early Intervention clinic* for assessment, which may lead to some clients receiving hormone blockers.**

2) A second group are usually referred after puberty starts, and those clients will be assessed in the general GIDS clinic, and if they are assessed as having gender dysphoria, may be referred to the Paediatric Endocrine Liaison team's *standard clinic,* which may lead to some receiving hormone blockers in the first instance.		
Theme	**Questions**	**Comments** (Include source of information and details of assumptions made and any issues with the data)
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. In England, the number of referrals to the service is increasing, with some 1400 new referrals projected for 15/16.
	K1.2 What is the number of patients eligible for this treatment under currently routinely commissioned care arrangements?	K1.2 The current clinical protocol in England is that the service prescribes 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. This is a not routinely commissioned policy, but if in the future it is changed to commission from age 15 instead of 16, perhaps as a result of a clinical trial or other new evidence, then only a very small number of clients would be in scope for this policy - that is only those who have: a) been seen in the service's Paediatric Endocrine Liaison team's Early Intervention Clinic (which is usually from the age of 12-13) b) received hormone blockers for one year or more, c) are able to give informed consent

		d) been assessed as having persistent GD e) 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. This policy proposition is to Not Routinely Commission cross sex hormones below the age of 16, although if this is changed in the future, following the outcome of the clinical trial that the provider proposes to undertake, this would impact upon 40 clients in year one (on the basis that this is the number of patients who are already in the system, that is are already receiving hormone blockers via the Early Intervention Clinic and would reach age 15 in 2016/17 and if there was a 20% increase in referrals in 2016/17).
	K1.3 What age group is the treatment indicated for?	K1.3 Adolescent clients from age 15 who meet the criteria set out in K1.2
	K1.4 Describe the age distribution of the patient population taking up treatment?	K1.4 Clients aged between a)15 years and b)the 16th birthday
	K1.5 What is the current activity associated with currently routinely commissioned care for this group?	K1.5 There are some 21 clients aged 16+ who currently receive cross sex hormones, having previously been receiving the hormone blocker through the Early Intervention Clinic. This is separate to a larger cohort of clients who receive cross sex hormones having only attended the standard clinic from the age of 15 and have been on the blocker for a

		min of one year – these clients are out of scope of this policy proposition which is only for those clients who have accessed the Early Intervention Clinic from around the age of 12 upwards. (See note to reader at the introduction).
	K1.6 What is the projected growth of the disease/condition prevalence (prior to applying the new policy) in 2, 5, and 10 years	K1.6 the number of clients who are eligible for cross sex hormones (circa 3-5% of all referrals) represent only a small minority of the total number of referrals to the PELT's Early Intervention Clinic. Current estimates are that the prevalence 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 rose 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	K1.7 Given the reasons stated in K1.6, the demand for this service is increasing as compared to other paediatric services. Growth rates are predicted to continue to rise, although the figure is likely to be less than the on average rise (50% per annum since 2009 to 2014/15 and 100% in 2015/16) as it is expected to level off. A flat figure of 20% over the next ten years is estimated. Based on the experience of the Dutch service, it may be that there is a change in the profile of referrals to the service – as there, the number of young people who enter the service and who will be eligible for the Early Intervention Clinic has increased over time as a proportion of the total, whilst the number referred post 15 years of age has decreased.

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<td>K1.8 How is the population currently distributed geographically?</td>
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If this referral profile takes place in England, over time the number of young people who will be eligible for cross sex hormones at 15 will increase year on year rather than decrease.

Taking this into account, and noting that this is a Not Routinely commissioned policy proposition, if in future years a routine commissioning policy was created to commission cross sex hormones from 15 for those clients who met the criteria in K1.2, then the numbers would be as follows:

<table>
<tr><td>If base year is 2016/17 for example, of 40 patients</td><td rowspan="5">Growth rate (20%)</td><td>Number of patients in scope for cross sex hormones at 15 years</td><td>Total number of additional appointments needed (2 extra appointments per patient)</td></tr>
<tr><td>1 year (2016/17)</td><td>40</td><td>80</td></tr>
<tr><td>2 years (2018/19)</td><td>48</td><td>96</td></tr>
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K1.8 Currently more referrals are received from the Midlands and the
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		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 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?	K2.1 The policy proposition is for a Not Routinely Commissioned Policy.
	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 rose to 100% in 15/16. (New referrals in 2014/15 were 697 and the projected outturn of new referrals for 15/16 is 1400).
	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 details	K2.3 Presentations are assumed to be related to population size rather than any geographic hot spots per se.
	K2.4 What is the resulting expected net increase or decrease in the	K2.4 At present this is difficult to quantify but is estimated to be as shown at K1.7, which is:

	number of patients who will access the treatment per year in year 2, 5 and 10?	If base year is 2016/17 of 40 patients, a flat growth rate over 10 years is assumed of 20% to take into account likely fluctuations over time.
K3 Activity	K3.1 What is the current annual activity for the target population covered under the new policy? Please provide details in accompanying excel sheet K3.2 What will be the new activity should the new policy be implemented in the target population? Please provide details in accompanying excel sheet 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	K3.1 Total new referrals forecast outturn for 2015/16 is 1400 patients. Although this is a Not Routinely commissioned policy, if it were to be changed in future years, 40 extra people would be in scope for cross sex hormones from their 15th birthday based on a predicted 20% increase in referrals in 2016/17 to 1680. K3.2 see K1.7 K3.3 Continue with psychological counselling or hormone blockers alone.
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. Kk4.2 What are the current treatment	K4.1 No formalised commissioned activity for the prescribing of cross sex hormones under the age of 16. **K4.2** **K4.2.1 Criteria for acceptance into the general GIDS service:**

	access criteria?	• 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. • Referrals will be accepted if there is evidence of features consistent with a diagnosis of GD and identified risk is being managed locally; • 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 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, • There is support from the family or carers, • 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, • 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**

		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 • impact on fertility has been discussed and the implications are understood • some evidence of presentation coherent with gender identity, for example deed poll name change • the client is engaged in or taking steps to secure, meaningful activity such as education or employment, accepting that societal limitations may affect this • 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 • the client is in good physical health • 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 • the client has not smoked for a minimum of three months • the client is therapeutically engaged with the service • at least two clinicians agree on the suitability of the client receiving cross-sex hormones
	K4.3 What are the current treatment stopping points?	**K4.3 Stopping points:** 1 If there are any concerns about the client's physical health such as

		low bone density 2. If the family /young person does not attend regular follow ups at the Paediatric Endocrine Liaison Clinic and/or the GIDS general clinics at the Tavistock as agreed in their care plan. 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. 4. If there are physical contraindications that require further investigation. 5. If the client decides to cease treatment for any reason
K5 Comparator (next best alternative treatment) Patient Pathway	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. K5.2 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.	K5.1 Continue with psychological counselling or hormone blockers alone until the 16th birthday. 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.

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<td>K6 New Patient Pathway</td>
<td>K6.1 Describe or include a figure to outline associated activity with the patient pathway for the proposed new policy

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 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</td>
<td>K6.1 This is a Not Routinely Commissioned Policy proposition but if this were to be changed in future years, the impact would be:

As K1.7

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K6.2 Not applicable</td>
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	having test to determine likely success). If possible please indicate likely outcome for patient at each stopping point.	
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? *e.g. service capacity*	K7.1 Acute Trust: Inpatient No Outpatient Yes – 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	k8.1 In which datasets (e.g. SUS/central data collections etc.) will activity related to the new patient pathway be recorded?	K8.1 bespoke report.

	K8.2 How will this activity related to the new patient pathway be identified?(e.g. ICD10 codes/procedure codes)	K8.2 procedure codes
K9 Monitoring	K9.1 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 K9.2 If this treatment is a drug, what pharmacy monitoring is required? K9.3 What analytical information /monitoring/ reporting is required? K9.4 What contract monitoring is required by supplier managers? What changes need to be in place? K9.5 Is there inked information required to complete quality dashboards and if so is it being incorporated into routine performance monitoring?	K9.1 No K9.2 Standard monitoring via senior pharmacist as now K9.3 As now K9.4 As now, no change K9.5 No K9.6 No

	K9.6 Are there any directly applicable NICE quality standards that need to be monitored in association with the new policy? K9.7 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*	K9.7 Not at present
Section L - Service Impact		
Theme	**Questions**	**Comments** (Include source of information and details of assumptions made and any issues with the data)
L1 Service Organisation	L1.1 How is this service currently organised (i.e. tertiary centres, networked provision) L1.2 How will the proposed policy change the way the commissioned service is organised?	L1.1 There is a single national designated provider which subcontracts with an acute provider for the Paediatric Endocrine Liaison Clinics L1.2 There will be no change to the current arrangements
L2 Geography & Access	L2.1 Where do current referrals come from? L2.2 Will the new policy change	L2.1 Referrals are accepted from a range of professionals including CAMHS professionals, GPs, secondary care clinicians including paediatricians and gynaecologists, schools and colleges of further education. L2.2 Referrals should still come from the same source.

	/ restrict / expand the sources of referral?	
	L2.3 Is the new policy likely to improve equity of access?	L2.3 Yes
	L2.4 Is the new policy likely to improve equality of access / outcomes?	L2.4 Yes
L3 Implementation	L3.1 Is there a lead in time required prior to implementation and if so when could implementation be achieved if the policy is agreed?	L3.1 This is not an issue as the policy proposition is for a Not Routinely Commissioned position, but if it were to be changed in future years, it would be phased in.
	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 This is not an issue as the policy proposition is for a Not Routinely Commissioned position, but if it were to be changed in future years, then yes, there would need to be an increase in the number of clinic appointments available and clinical nurse specialist time.
	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? L3.6 Is there a change in provider / inter-provider governance required? (e.g. ODN arrangements / prime contractor) L3.7 Is there likely to be either an increase or decrease in the number of commissioned providers? 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)	L3.5 No L3.6 No L3.7 No change. L3.8. Via the contracting process.
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

Section M - Finance Impact		
Theme	**Questions**	**Comments** (Include source of information and details of assumptions made and any issues with the data)
M1 Tariff	M1.1 Is this treatment paid under a national prices*, and if so which?	M1.1 There is a block contract for the GIDS service, although there is separate funding stream within the contact for an outpatient 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 policy?	M1.6 No
M2 Average Cost per	M2.1 What is the revenue cost per patient in year	M2.1 This not an issue as the policy proposition is to

Patient	1? M2.2 What is the revenue cost per patient in future years (including follow up)?	Not Routinely Commission, but if it were to be changed in future years, then the cost would be £472 per patient x 2 extra clinic attendances per person as clients would be seen twice in the 12 month period. M2.2 As now – no additional costs over and above current contract costs as this proposal is only to introduce the treatment two months in advance of the current date of introduction.
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? M3.2 Where this has not been identified, set out the reasons why this cannot be measured?	M3.1 There is no cost in 16/17 as this is a Not Routinely Commissioned policy, but if it were to be changed in future years, then it would be a cost pressure. M3.2 It can be measured.
M4 Overall cost impact of this policy to the NHS as a whole	M4.1 Indicate whether this is cost saving, neutral, or cost saving for other parts of the NHS (e.g. providers, CCGs) M4.2 Indicate whether this is cost saving, neutral, or cost pressure to the NHS as a whole?	M4.1 There is no cost in 16/17 as this is a Not Routinely Commissioned policy, but if it were to be changed in future years, then it would be a cost pressure. M4.2. There is no cost in 16/17 as this is a Not Routinely Commissioned policy, but if it were to be changed in future years, then it would be a cost pressure. M4.3 It can be measured

	M4.3 Where this has not been identified, set out the reasons why this cannot be measured? M4.4 Are there likely to be any costs or savings for non NHS commissioners / public sector funders?	M4.4 GPs will incur the cost for up to 12 additional months treatment per client, (total cost 12 months of Cross Sex Hormones = £2,460)* but for those few GPs affected (30-40 nationally in 16/17), they are likely to have only one patient. *Testosterone (female to male clients) - Estradiol valerate tablets assuming 4mg daily =£80/year approx Oestrogen (male to female) - Sustanon 250mg x three weekly =£43/year.
M5 Funding	M5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified	*There is no impact currently but if in future years it is decided to make this a routinely commissioned policy, the costs would be sourced from NHS England Prioritisation monies*
M6 Financial Risks Associated with Implementing this Policy	M6.1 What are the material financial risks to implementing this policy? M6.2 Can these be mitigated, if so how? M6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios	*No material financial impact is expected* *Not applicable* *Not applicable*

M7 Value for Money	M7. M7.2 What issues or risks are associated with this assessment?	*M7.2 None*
M8 Cost Profile	M8.1 Are there non-recurrent capital or revenue costs associated with this policy? M8.2 If so, confirm the source of funds to meet these costs.	None *None*