

Clinical Commissioning Policy: Prescribing of Cross-Sex Hormones as part of the Gender Identity Development Service for Children and Adolescents

Reference: NHS England: 16046/P



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Finance		

Publications Gateway Reference: 05527s

Document Purpose	Policy
Document Name	Clinical Commissioning Policy 16046/P
Author	Specialised Commissioning Team
Publication Date	22 August 2016
Target Audience	CCG Clinical Leaders, Care Trust CEs, Foundation Trust CEs , Medical Directors, Directors of PH, Directors of Nursing, NHS England Regional Directors, NHS England Directors of Commissioning Operations, Directors of Finance, NHS Trust CEs

Additional Circulation List

Description	Routinely Commissioned - NHS England will routinely commission this specialised treatment in accordance with the criteria described in this policy.
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Cross Reference	This document is part of a suite of policies with Gateway Reference 05527s.
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Superseded Docs (if applicable)	N/A
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Action Required	N/A
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Timing / Deadlines (if applicable)	N/A
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Contact Details for further information	england.specialisedcommissioning@nhs.net
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Document Status

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Clinical Commissioning Policy: Prescribing of Cross-Sex Hormones as part of the Gender Identity Development Service for Children and Adolescents

First published: August 2016

**Prepared by NHS England Specialised Services Clinical Reference Group for
Paediatric Medicine**

Published by NHS England, in electronic format only.

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Policy Statement

NHS England will, as part of the Gender Identity Development Service for Children and Adolescents, commission cross sex hormones for young people with continuing gender dysphoria from around their 16th birthday subject to individuals meeting the eligibility and readiness criteria as set out in Section 6 of this document. In exercising this discretion, the specialist multi-disciplinary team will be cognisant that international guidelines recommend the prescribing of cross sex hormones to gender variant young people at 'around 16 years'. In creating this policy NHS England has reviewed this clinical condition and the options for its treatment. It has considered the place of this treatment in current clinical practice, whether scientific research has shown the treatment to be of benefit to patients, (including how any benefit is balanced against possible risks) and whether its use represents the best use of NHS resources. This policy document outlines the arrangements for funding of this treatment for the population in England.

Equality Statement

Promoting equality and addressing health inequalities are at the heart of NHS England's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and
- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities

Plain Language Summary¹

About gender dysphoria

Gender dysphoria is a condition where a person experiences discomfort or distress because there is a mismatch between their natal (assigned) sex and the gender with which they identify.

Gender dysphoria can be more distressing in adolescence due to the pubertal development of secondary sex characteristics and increasing social divisions between genders. As a result, adolescents can be at risk of self-harm, despair and can become vulnerable to relationship difficulties, social isolation and stigma.

NHS England commissions a specialist multi-disciplinary gender identity development service for children and young people up to their 18th birthday.

About the treatment

Cross sex hormones are drugs that may be prescribed to a person with gender dysphoria. The drugs are consistent with the individual's experienced gender as compared to the assigned gender. A trans man (female to male) may be prescribed a masculinising hormone; and a trans female (male to female) may be prescribed a feminising hormone.

NHS England will commission cross sex hormones for young people who meet the eligibility and readiness criteria described in this policy document from around their 16th birthday.

NHS England has explored whether it would be appropriate to prescribe cross sex hormones to gender variant young people below 16 years of age. Given the very limited evidence (including from other countries) about the effects and harms of prescribing cross sex hormones to young people under 16 years, the policy stipulates that young people should be aged around 16 years to receive a prescription for these drugs.

¹ NHS England acknowledges that language in this area is evolving and is different depending on the stakeholder's perspective. It is currently most appropriate to refer to people's assigned sex at birth rather than saying natal or biological sex, although those words also feature in this document. In addition, cross sex hormones are now referred to as gender affirming hormones. Once a person has been accepted into the service, they are referred to as a client.

1 Introduction

This document describes the evidence that has been considered by NHS England in formulating a clinical commissioning policy for commissioning cross sex hormones in the treatment of gender dysphoria in adolescents who are aged “around 16 years” as part of the Gender Identity Development Service for Children and Adolescents.

In England and other European countries, the current treatment options for gender dysphoria in adolescents, following an initial psychological assessment and where hormone therapy is considered appropriate, include:

- Gonadotropin-releasing hormone analogues (GnRH), referred to in this document as hormone blockers, which suppress further pubertal development. The decision to prescribe is based on the client’s clinical presentation of gender dysphoria, psychological assessment and Tanner staging. Tanner staging is a scale of physical development in children, adolescents and adults.
- For some individuals, this may be followed by the partially reversible use of cross sex hormones for those who have continuing gender dysphoria and who wish to proceed with gender reassignment in later life.
- A move to the final step of irreversible sex alignment surgery may follow a few years later, typically at an age greater than 18 years and is delivered by adult gender identity services.

2 Definitions

Gender dysphoria: Gender dysphoria is where a person experiences discomfort or distress because there is a mismatch between their experienced gender as compared with their assigned sex and its associated physical primary and secondary sex characteristics.

Hormone blockers: These are gonadotrophin releasing hormone analogues which are synthetic (man-made) hormones that suppress the hormones naturally produced by the body and in doing so, suppress puberty, thereby reducing the level of puberty-related anxiety in an individual with gender dysphoria. The effects of treatment with

hormone blockers are considered to be fully reversible but there may be a delay in achieving a return to the previous state, including fertility.

Cross sex hormones: These are gender affirming hormones prescribed for an individual that are consistent with the experienced gender as compared to the assigned gender. For example:

- a trans man (female to male) or a non-binary person, assigned female, may be prescribed testosterone, which is a masculinising hormone,
- a trans woman (male to female) or a non-binary person, assigned male, may be prescribed oestrogen, which is a feminising hormone.

A careful assessment is required in each case, as some of the effects of cross sex hormones are irreversible (including possible sterility) and there are some risks, such as impaired growth and bone development.

3 Aims and Objectives

This clinical commissioning policy defines the criteria for access to cross sex hormones for gender variant young people.

The objective was to ensure evidence-based commissioning with the aim of improving outcomes and ensuring the safety of young people with continuing gender dysphoria.

4 Epidemiology and Needs Assessment

Gender variance is not uncommon. A survey of 10,000 people undertaken in 2012 by the Equality and Human Rights Commission found that 1% of that population was gender variant to some extent.

Gender dysphoria during childhood does not inevitably continue into adulthood, though the continuation into adulthood appears to be much higher for adolescents.

The incidence and prevalence of gender dysphoria in adolescence is difficult to ascertain because it includes all forms of gender non-conformity. Formal epidemiological studies on gender dysphoria 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. The numbers vary widely across studies, probably reflecting differences in methodology and differences between countries in treatment availability and the criteria for treatment eligibility. Estimates of the prevalence of gender dysphoria in adolescents range from a lower estimate of 1:2000 (or about 0.05%) in the Netherlands and Belgium (Olyslager et al 2007) to 1.2% in New Zealand (Clark et al 2014). These numbers are based on those who identify as transgender.

Referrals to England's designated Gender Identity Development Service for children and young people rose by 32% between 2007 and 2012 and there was an increase of 104% between 2014/15 and 2015/16 (to around 1400 referrals in 2015/16). Although children are sometimes referred from around 3 years, the increase is largely in the 14+ age group. The reasons for such a significant increase are not well understood, but are commonly attributed to increased awareness amongst parents and professionals, increased awareness amongst young people including through social media, and wider social acceptance of transgender issues.

5 Evidence base

Among adolescents who are referred to gender identity clinics, the number considered eligible for early medical treatment — starting with hormone blockers to suppress puberty in the first Tanner stages — differs among countries and clinics. Not all clinics offer puberty suppression. If such treatment is offered, the pubertal stage at which adolescents are allowed to start varies from Tanner stage 2 to stage 4 (Delemarre-van de Waal & Cohen-Kettenis, 2006). The percentages of treated adolescents are likely to be influenced by *inter alia*: the organisation of health care; commissioning arrangements; cultural differences; opinions of health professionals; and diagnostic procedures offered in different settings.

The NHS in England has commissioned the prescribing of cross sex hormones to gender variant young people from their 16th birthday for some years. In 2016 NHS England reviewed the available evidence on the use of cross sex hormone therapy for adolescents with continuing gender dysphoria after their 15th birthday. The

systematic literature search identified 54 studies. Many of these were expert commentaries. Fourteen studies met the review criteria and were appraised in detail.

The four questions considered were:

1. What are the ethical and developmental effects and harms (including consent, outcome of gender dysphoria and the developing brain) of cross sex hormone therapy for adolescents after their 15th birthday with persistent gender dysphoria?

The review found limited available evidence on comparative effects and harms of initiating cross sex hormones at the 15th birthday compared to initiating cross sex hormone therapy at the 16th birthday or older. The body of available evidence comprises case series, cross sectional and cohort studies of individuals treated in tertiary centres in the Netherlands, United States and Canada. None of the studies identified in the evidence review investigated the harms of not providing cross sex hormone treatment in the age subgroup of interest.

Some studies included a few cases of younger patients (below 16 years) beginning cross sex hormones, although this subgroup was not separately analysed.

Complications

Khatchadourian et al. (2014) retrospectively examined the treatment of gender dysphoric adolescents in Canada. Federal legislation permits consent to treatment below the age of 16 years, so this case series had less constraints on the age at which cross sex hormone treatment is started. However, the median age at the start of cross sex hormones for natal [assigned] males was 17.9 years with a range of 13.3 to 22.3 years and for natal [assigned] females 17.3 years with range of 13.7 to 19.8 years. No subgroup analysis was undertaken to compare those starting cross sex hormones before and after the 16th birthday. Of the 84 patients who initiated hormone blockers, 63 proceeded to receive cross sex hormones (87% of total assigned females and 65% of assigned males in the study).

Cross sex hormones were generally well tolerated in assigned males, although twelve of the 39 assigned female patients had minor complications from male cross

sex hormones: seven developed severe acne, one developed androgenic alopecia, three had mild dyslipidaemia and one had mood swings.

Three of these patients stopped cross sex hormones; two because of concomitant psychiatric comorbidities and one because of distress due to androgenic alopecia. The authors did not analyse any factors that could be potentially linked with these side effects, including age.

In Holland, the clinical protocol allows the use of cross sex hormones from 16 years of age, with the mean age of initiation being 16.4 to 16.7 years, though the lowest age of initiation ranged between 13.9 to 14.9 years on a case by case basis (de Vries et al., 2011, 2014; Klink et al., 2015).

Executive functioning

Staphorsius et al. (2015) in a large case control study of 84 adolescent patients (13-17 years) demonstrated that hormone blockers did not adversely impact executive function. The Tower of London performance scores (that are used to assess reaction times and accuracy of functioning) did not differ significantly from the untreated sub group. Functional magnetic resonance imaging (MRI) and region-of-interest analyses showed that hormone blocker treated adolescents showed sex differences in neural activation similar to their assigned sex control groups in contrast to untreated adolescents with gender dysphoria who did not show significant sex differences in task load-related activation.

Bone mineral density

Klink et al. (2015), in a case series of 34 patients in the Netherlands reported recovery in bone mineral density scores from treatment with hormone blockers during cross sex hormone treatment for both assigned males and assigned females, although the Z score at age 22 years remained lower than at the start of the treatment (0.2 at start to -0.3 at 22 years). An earlier Dutch study (Delemarre-van de Waal et al., 2006) had reported a significant decrease in the height standard deviation score and a slowing down of height velocity under hormone blockers (GnRHa) therapy. Neither study followed patients long enough to confirm whether peak bone mass was delayed or permanently reduced. Once cross sex hormones were started, there was a clear growth spurt with androgen therapy, but not with

oestrogen. Many factors (including a differing dose-response relationship depending on the hormone regime, age and/or Tanner stage at suppression, and delayed growth response with oestrogen outside the study window) could explain this difference in growth potential and bone mass recovery. However, these potential confounders were not addressed in the studies.

Psychological functioning

The impact on the psychological functioning and well-being of the adolescent throughout the gender dysphoria remains a key issue, especially given the high prevalence of psychiatric comorbidity.

Studies report that 22% to 44% of adolescents with gender dysphoria have significant psychiatric comorbidities including depression and anxiety (de Vries et al., 2011; Spack et al., 2012). De Vries et al. (2014) examined changes in psychological functioning throughout the treatment span. The study reported on the psychological functioning, subjective and objective well-being of 55 adolescents (age at start of cross sex hormones, mean 16.7, range 13.9 to 19.0) before administration of hormone blockers, before cross sex hormones and one year after cross sex hormones and gender reassignment surgery, with a total mean follow-up of seven years per patient. Global functioning in the subjects improved after hormone blockers and continued to improve after cross sex hormone initiation. Dissatisfaction with body image and levels of gender dysphoria were unchanged with hormone blockers, but decreased after starting cross sex hormones. Depression levels decreased after starting hormone blockers, but partially increased after starting cross sex hormones and prior to sex realignment, with assigned females demonstrating higher levels of depression. Anxiety levels appeared to increase after starting cross sex hormones but anger levels decreased.

Studies on psychological functioning have potential biases coming from many other factors impacting psychological wellbeing in the period of time before, during and after puberty. Limitations of the study referred to above include its single-arm study design and the potential confounding of age and other social and developmental factors which may directly or indirectly impact psychological functioning especially during teenage years.

Ethical review

Abel (2014) considered the key ethical principles affecting decisions about early prescribing of cross sex hormones. The principle of non-maleficence (“first, do no harm”) offers the strongest ethical argument against early cross sex hormone therapy because the long-term effects of this are not well known and it has the potential for sterility. The assessment of an individual must therefore consider the balance of the consequences of the treatment, including the benefits versus the potential harms. Hormone blockers, by contrast, have largely been considered free of long-term harm based on generations of follow-up studies with the large population of individuals prescribed such drugs for precocious puberty.

Beneficence (i.e. the obligation of physicians to help their patients) is another key principle in considering early cross sex hormone therapy. While delaying hormone therapy may conform to the principle of non-maleficence for this group, the significant prevalence of patients stopping treatment and the inability to predict which will continue with treatment, detracts from the argument for prescribing cross sex hormones.

Given the possibility of patients stopping treatment, physicians must consider the situation where cross sex hormone therapy renders permanent harm in a gender non-conforming young person in whom the gender dysphoria dissipates. Helping an adolescent to appreciate the seriousness of infertility is an important ethical obligation and one complicated by the fact that the adolescent’s developing brain is generally more limited than the adult brain in its ability to weigh long term consequences (Abel et al., 2014). The task becomes more complex given the prevalence of autism (Kaltiala-Heno et al., 2015) and psychiatric comorbidities that can be as high as 22% to 44% amongst gender dysphoric adolescents (de Vries et al., 2011; Spack et al., 2012).

For this reason, consideration of the long term impacts, including on fertility, has been included in the eligibility and readiness criteria described in this policy document, and will be assessed in each individual.

2. Are the effects and harms of cross-sex hormone therapy for adolescents after their 15th birthday with continuing gender dysphoria different for biologically [assigned] male and biologically [assigned] female patients?

The effect of cross sex hormones is expected to be different in assigned male and female subjects. Evidence is not available regarding any difference on response to cross sex hormones specifically below the age of 16 years.

In the available evidence, with respect to reversing some of the effects of gonadal suppression, Klink et al. 2015 report minimal difference in response to cross sex hormones in assigned female and assigned male patients in improving bone density.

For assigned females, lumbar spine area bone mineral density (LS aBMD) scores were below the population mean at the start of the treatment and in assigned males LS aBMD score was normal at the start of the treatment but decreased during hormone blocker therapy. During cross sex hormone therapy, LS aBMD improved for both groups. However the z score at age 22 years remained lower than that at start of the treatment.

A cross-sectional survey on psychological comorbidities on 105 patients with gender dysphoria in the Netherlands (de Vries et al. 2011) found that assigned males had higher rates of social phobia and mood disorders. In contrast, in two potentially overlapping case series by the same lead author (de Vries et al., 2011, 2014), assigned male subjects were reported to have significantly lower levels of gender dysphoria, anger, anxiety, depression and higher levels of body image satisfaction and global functioning, than assigned female subjects. Both genders showed improvement in symptoms with cross sex hormones.

3. Are the effects and harms of cross sex hormone therapy for adolescents after their 15th birthday with continuing gender dysphoria different for patients in whom irreversible physical changes have already occurred after onset of puberty?

There was no relevant evidence available as part of this review. Rosenthal et al. (2014) expressed the opinion that *“Occasionally, some gender-dysphoric youth first come to medical attention when they are Tanner 4/5 but below 14 years of age.*

Such individuals would be candidates for pubertal blockers (e.g. to stop menses in a female to male adolescent), but without supportive outcome data, not currently candidates for cross-sex hormones in most circumstances”.

4. How does length of time on the analogue blocker prior to treatment with cross-sex hormones relate to different presentations of gender dysphoria (early/late presentations)?

The length of time on hormone blockers varied amongst different studies reviewed. There was no direct information on the impact of length of time on gender dysphoria presentation. One study, de Vries et al. (2011) assessed patients at the start of puberty suppression using hormone blockers and again two years later at the start of cross sex hormones and found no change in levels of gender dysphoria or body image satisfaction but statistically significant improvement in depression and global functioning for most patients. Prevalence of other behavioural presentations such as anger, anxiety remained unchanged.

6 Criteria for Commissioning

Cross sex hormones may be prescribed to younger people with gender dysphoria from around their 16th birthday subject to individuals meeting the eligibility and readiness criteria, noting that in exercising this discretion, the specialist multi-disciplinary team will be cognisant that international guidelines recommend the prescribing of cross sex hormones to gender variant young people at “around 16 years”.

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	Eligibility and readiness criteria:	Reason for this criterion:
1	<p>The client has been assessed by the appropriate specialist multi-disciplinary team over a period of time* and fulfils the criteria for a diagnosis of Gender Dysphoria. This includes those clients who are non-binary or have evidence of continuing Gender Dysphoria.</p> <p>*The duration of the assessment to be determined by the clinical team as relative to the needs of the client.</p>	<p>To ensure that the client is highly likely to continue to identify in the experienced gender, meaning that cross sex hormones are an appropriate treatment in the long term.</p>
2	<p>There is some evidence of presentation coherent with gender identity and intention to live in their preferred gender in the long term.</p>	<p>To ensure that the client is aware that changing their body alone will not necessarily make it easier to make the transition to the gender with which they identify.</p>
3	<p>The client has been receiving gonadotropin-releasing hormone analogues (blockers) for an agreed period of time under the care of the appropriate specialist multi-disciplinary team.</p>	<p>To ensure that the impact of the hormone blockers is understood in relation to the possible use of cross sex hormones; the duration of hormone blocker treatment will be considered on a case by case basis.</p> <p>To ensure that whilst the client is on hormone blockers, they have engaged in discussions with clinicians and with others about their gender identity and have had an appropriate amount of time in the view of the multi-disciplinary clinical team to explore their gender identity</p>

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		before seeking further interventions.
4	The client is actively engaging with the appropriate specialist multi-disciplinary team and regularly attending appointments.	To ensure that the client has ongoing opportunities to explore their options and manage any arising issues.
5	The client is in good physical health, and preferably is not smoking.	<p>To ensure that there are no health contraindications for taking cross sex hormones.</p> <p>To ensure that the client understands that smoking can have a negative effect on the development of the secondary sex characteristics that cross sex hormone treatments are intended to affect.</p>
6	The impact on the client's fertility has been discussed with them; they understand that the treatment will affect their fertility, and that if required by the client, a request is made to the GP to refer on to licensed NHS fertility experts for discussions on egg/sperm retrieval and storage.	To ensure that the client is fully aware that cross sex hormone treatment may compromise their fertility in the long term; therefore it may be preferable for them to talk to their GP about egg or sperm retrieval via a licensed NHS fertility service - if this has not already been undertaken prior to starting on hormone blocker treatment.

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7	<p>That the client is able to give informed consent and has cognitive and emotional maturity. That is, they can understand the long term implications of cross sex hormone treatment, can retain this knowledge, can weigh in the balance the benefits and drawbacks of the treatment and can come to a decision. Particular care will be taken to ensure these conditions are met with clients who have a learning disability and those for whom English is a second language.</p>	<p>To ensure that the client can comprehend as fully as possible what the physical treatment will offer, has sufficient autonomy and emotional resilience to participate in decision making and meets the Fraser guidelines.</p>
8	<p>That the client is interacting with others and engaging socially (such as by attending school or college or is seeking employment, accepting that societal limitations may affect this).</p>	<p>To ensure that the client is generally able to engage in the social aspects of daily living as this may help them to better manage their transition to the gender with which they identify.</p>
9	<p>Ideally there will be support for the client for example, from one or both parents (the family)/carers, or social support if the client is a 'Looked After Child', and the Local Authority has been consulted.</p>	<p>To ensure that the client will receive support at home with both managing their physical transition and in coping with the side effects of treatment. It is recognised that some clients approaching adulthood may not have this support – in these cases, the role of wider social networks will be taken into consideration.</p>
10	<p>Associated difficulties such as a psychotic episode, drug addiction or self-harming are not escalating.</p>	<p>To ensure that such difficulties are taken into account when considering the impact on a client's ability to manage the effects of cross sex</p>

		hormones; such difficulties will be reviewed on a case by case basis.
11	At least two specialist clinicians, including a consultant endocrinologist and a senior psychosocial clinician, who are directly involved in the client's care, agree on the suitability of the client receiving cross-sex hormones based on the consideration of these eligibility and readiness criteria.	To ensure that the client understands that there is limited clinical evidence on the effects and harms of prescribing cross sex hormones below their 16 th birthday. Also that cross sex hormone treatment is a significant decision with long term indications.

Clinical contra-indications

- Abnormalities in status or timing of pubertal development or other physical contraindications that require further investigation;
- Self-administration of hormone blockers or cross sex hormones out-with an NHS prescription;
- If there are any concerns about the client's physical health such as low bone density;
- If the client and their family/carers do not attend regular follow up appointments at the Paediatric Endocrine Liaison Clinic and/or the general clinics at the Gender Identity Development Service as agreed in the client's individualised care plan;
- If the client is having a significant psychotic episode or has another 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; in such cases, if the hormone treatments have begun, these may be paused whilst the young person is being supported by other services to better manage their condition;
- If there are physical contraindications that require further investigation;

- If the client decides to cease treatment for any reason.

7 Patient Pathway

A recommendation for hormone therapy will form part of the client's Individual Care Plan, and must be agreed between the specialist multi-disciplinary team and the young person and their family/carers.

Clients who are assessed as having continuing gender dysphoria may be referred to the Paediatric Endocrine Liaison Team for review, which may lead to some clients receiving hormone blockers under the care of the specialist multi-disciplinary team.

Before any physical interventions are considered for adolescents, extensive exploration of psychological, family, and social issues should be undertaken. The duration of this exploration may vary considerably depending on the complexity of the situation. A staged process is recommended to keep options open through the fully reversible intervention of the use of hormone blockers to suppress oestrogen or testosterone production; and the partially reversible intervention of hormone therapy to masculinise or feminise the body. Moving from one stage to another should not occur until there has been adequate time for adolescents and their parents to assimilate fully the effects of earlier interventions.

In some cases, the referral to the Paediatric Endocrine Liaison Team is made for the purpose of physical assessment to exclude a disorder of sex development or other endocrine conditions.

Hormone therapy will be prescribed by the client's General Practitioner on the advice of the specialist multi-disciplinary team.

Transfer into the adult pathway may occur from the client's 17th birthday.

8 Governance Arrangements

There must be appropriate specialist multi-disciplinary team composition at all stages of the pathway.

The provider must be compliant with the British Society for Paediatric Endocrinology and Diabetes', UK Standards for Paediatric Endocrinology (2010).

The provider will have relevant documented policies, including for safeguarding children; clinical audit; clinical risk assessment; consent; complaints; and prescribing and administration of medicines.

The recommendation from the specialist multi-disciplinary team to prescribe cross sex hormone therapy must be made by a medically-qualified professional.

NHS England expects General Practitioners (GP) to co-operate with the specialist multi-disciplinary team to prescribe cross sex hormone therapy for their patients. They are also expected to co-operate in patient safety monitoring, by providing basic physical examinations (within the competence of GPs) and blood tests recommended by the specialist multi-disciplinary team. The specialist multi-disciplinary team is expected to assist GPs by providing relevant information and support, including the interpretation of blood test results.

9 Mechanism for Funding

The funding and commissioning will be managed through the relevant local NHS England Specialised Commissioning Team.

Clinical Commissioning Groups fund drug costs in relation to the hormone cost for each patient.

10 Audit Requirements

NHS England acknowledges the strength of views for an alternative, criteria-based approach and recognises that in some administrations, in some circumstances, cross sex hormones are prescribed to younger people. In response, NHS England requires standardised data collection, (inside and outside of a clinical trial), in order to continue to develop the evidence base in the context of an ethically approved study. This will include the feasibility and appropriateness of a criteria-based approach rather than an age basis approach. To facilitate this, providers will be required to submit data annually to NHS England and enter eligible patients into appropriate clinical trials.

11 Documents which have informed this Policy

Advice for Doctors Treating Transgender Patients, General Medical Council, 2016
Good Practice Guidelines for the Assessment and Treatment of Adults with Gender Dysphoria; Royal College of Psychiatrists, 2013.

Standards of Care, Version 7, World Professional Association for Transgender Health, 2012.

Endocrine Treatment of Transsexual Persons: An Endocrine Society Clinical Practice Guideline, Endocrine Society, 2009.

12 Date of Review

This clinical commissioning policy and the supporting evidence available at the time will be reviewed in 2019/20; or earlier if the proposed research study (see section 10) yields data that would support an earlier review.

References

Abel BS. 2014 Hormone treatment of children and adolescents with gender dysphoria: an ethical analysis. *Hastings Cent Rep* 44 Suppl 4:S23-7.

Clark, T.C., Lucassen, M.F.G., Bullen, P., Denny, S.J., Fleming, T.M., Robinson, E.M., Rossen, F.V., The Health and Well-Being of Transgender High School Students: Results from the New Zealand Adolescent Health Survey (Youth'12) *Journal of Adolescent Health* 55 (2014) 93-99.

Delemarre-van de Waal H.A., Cohen-Kettenis P.T. 2006 Clinical management of gender identity disorder in adolescents: a protocol on psychological and paediatric endocrinology aspects www.eje-online.org/content/155/suppl_1/S131.full

de Vries A.L.C., Doreleijers T.A.H., Steensma T.D., Cohen-Kettenis, P.T. 2011 Psychiatric comorbidity in gender dysphoric adolescents. *J Child Psychol Psychiatry* 52: 1195—1202

de Vries A.L.C., Steensma T.D., Doreleijers T.A.H., Cohen-Kettenis P.T. 2011 Puberty suppression in adolescents with gender identity disorder: a prospective follow-up study. *J Sex Med* 8(8):2276-83.

de Vries A.L.C., McGuire J.K., Steensma T.D., Wagenaar E.C.F., Doreleijers T.A.H., Cohen-Kettenis P.T. 2014 Young adult psychological outcome after puberty suppression and gender reassignment. *Pediatrics* 134(4):696-704.

Kaltiala-Heino R, Sumia M, Työläjärv M, Lindberg N. 2015 Two years of gender identity service for minors: overrepresentation of natal girls with severe problems in adolescent development. *Child Adolesc Psychiatry Ment Health*,9;9:9.

Khatchadourian K, Amed S, Metzger D.L. 2014 Clinical management of youth with gender dysphoria in Vancouver. *J Pediatr* 164(4):906-11

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Klink C.M, Heijboer A, van Trotsenburg M, Rotteveel J. 2015 Bone mass in young adulthood following gonadotropin- releasing hormone analog treatment and cross-sex hormone treatment in adolescents with gender dysphoria. *J Clin Endocrinol Metab* 100: 2. doi/10.1210/jc.2014-2439

Olyslager,F., Conway, L 2007 On the Calculation of the Prevalence of Transsexualism - paper presented at the World Professional Association for Transgender Health, Illinois,2007.

Rosenthal S.M. 2014 Approach to the patient: transgender youth: endocrine considerations. *J Clin Endocrinol Metab* 99(12):4379-89.

Spack NP, Edwards- Leeper L, Feldman HA, Leibowitz S, Mandel F, Diamond DA, Vance, Stanley R. 2012 Children and adolescents with gender identity disorder referred to a pediatric medical center. *Pediatrics* 129(3):418-25.

Staphorsius A.S., Kreukels B.P.C., Cohen- Kettenis P.T. ,Veltman D.J., Burke S.M., Schagen S.E.E., Wouters F.M., Delemarre-van de Waal H.A., Bakker J. 2015 Puberty suppression and executive functioning: An fMRI-study in adolescents with gender dysphoria. *Psycho-neuroendocrinology* 56: 190 – 199.