

## Specialised Services Circular

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### Primary Care responsibilities in relation to the prescribing and monitoring of hormone therapy for patients undergoing or having undergone Gender dysphoria treatments

<b>Circulation</b>	
<p><b>For action</b></p> <ul style="list-style-type: none"> <li>Area Team Directors</li> <li>Area Team Directors of Commissioning</li> <li>Area Team Heads of Specialised</li> <li>Area Team IFR Leads</li> <li>Area Team Finance Leads</li> <li>Area Team Pharmacists</li> </ul> <p>Area Teams to circulate to:</p> <ul style="list-style-type: none"> <li>Acute Trust Chief Executives;</li> <li>Mental Health Trust Chief Executives</li> <li>Acute Trust Medical Directors</li> <li>Mental Health Medical Directors</li> <li>CCG Medical Directors</li> <li>General Practitioners</li> <li>Gender Identity Services – Clinical Directors</li> </ul>	<p><b>For information</b></p> <ul style="list-style-type: none"> <li>Regional Directors of Commissioning</li> <li>Regional Heads of Specialised Commissioning</li> <li>Regional Finance Leads</li> </ul> <p>Clinical Reference Group Chair and Accountable Commissioner; Specialised Gender Identity Services</p>

## Background

Since April 2013, NHS England has been responsible for commissioning the specialised element of the gender dysphoria care pathway, currently delivered through the seven English specialised Gender Identity Clinics (GICs). GPs also have an integral role in providing care for people with gender dysphoria, delivering the non-specialised element of the pathway. They should work in co-operation with GICs to ensure that patients have access to a safe and effective care pathway. The responsibilities of NHS England with respect to the specialised element of the pathway are set out in the *Interim Gender Dysphoria Protocol and Service Guideline 2013/14* (this document may be downloaded via a link at the bottom of the following Web page: <http://www.england.nhs.uk/resources/spec-comm-resources/npc-crg/group-c/c05/>).

This circular is intended to provide clarity to GPs on the roles and responsibilities of specialist providers within the gender dysphoria care pathway, and to encourage collaboration between GPs and specialists in the delivery of care for trans and gender-variant people

Gender Identity Services are Specialised Services commissioned by NHS England. They are delivered by GICs, operating from seven centres in England; patients travel long distances to those centres in order to receive the service. GICs provide specialist assessment, co-ordinate provision of a wide range of treatments for gender dysphoria for people with atypical gender identity development, and provide some components of treatment. Interventions provided directly by GICs may include the following: co-ordination of the overall care pathway; psychological therapies; provision of advice on feminising or virilising endocrine therapies, referral for or provision of hair removal; referral for or provision of speech and language therapy; referral for surgical procedures; provision of recommendations to primary care on lifelong healthcare after completion of specialised service interventions, prior to discharge.

A key element of successful treatment for gender dysphoria is feminising or virilising endocrine therapy. GICs make recommendations for the prescription and monitoring of these therapies but do not directly prescribe them, or provide physical and laboratory monitoring procedures for patients. On page 11, the *Interim Gender Dysphoria Protocol and Service Guideline 2013/14* states that, "NHS England expects GPs to co-operate with their commissioned GICs and to prescribe hormone therapy recommended for their patients by the GIC. They are also expected to co-operate with GICs in patient safety monitoring, by providing basic physical examinations (within the competence of GPs) and blood tests recommended by the GIC. The GIC is expected to assist GPs by providing relevant information and support, including the interpretation of blood test results. Hormone therapy should be monitored at least 6 monthly in the first 3 years and yearly thereafter, dependant on clinical need."

GPs are encouraged to collaborate with GICs in the initiation and on-going prescribing of hormone therapy, and for organising blood and other diagnostic tests as recommended by the GICs. The responsibilities of specialist providers working in GICs are set out in the *Manual of Prescribed Specialised Services* (page 129, <http://www.england.nhs.uk/wp-content/uploads/2012/12/pss-manual.pdf>). Since 1<sup>st</sup>

April 2013, patients and GICs have reported that there has been an increase in the number of GPs declining to prescribe and monitor drug treatments for the treatment of gender dysphoria in people with atypical gender identity development (transsexual, transgender and gender non-conforming persons).

Typical drugs recommended by GICs include oestradiol preparations (e.g. transdermal oestradiol gels and patches, and oral oestradiol preparations), testosterone preparations (e.g. gels, and Sustanon® and Nebido® injection), gonadotropin releasing hormone analogues and depilatory agents (e.g. Vaniqa®); this list is not exhaustive. Apart from Sustanon®, there are no licensed products with an approved indication for the treatment of gender dysphoria. There is, however, extensive clinical experience of the use of these products in the treatment of gender dysphoria over decades, which provides evidence of tolerability and safety comparable with their use for approved indications.

In *Good practice in prescribing and managing medicines and devices (2013)* ([http://www.gmc-uk.org/guidance/ethical\\_guidance/14327.asp](http://www.gmc-uk.org/guidance/ethical_guidance/14327.asp)), the General Medical Council advises:

“ 69. Prescribing unlicensed medicines may be necessary where:

- There is no suitably licensed medicine that will meet the patient’s need, for example, where:
- There is no licensed medicine applicable to the particular patient. For example, if the patient is a child and a medicine licensed only for adult patients would meet the needs of the child; or
- A medicine licensed to treat a condition or symptom in children would nonetheless not meet the specific assessed needs of the particular child patient, but a medicine licensed for the same condition or symptom in adults would do so; or
- The dosage specified for a licensed medicine would not meet the patient’s need; or
- The patient needs a medicine in a formulation that is not specified in an applicable license.”

Their advice continues in paragraphs 70 to 72:

“ 70. When prescribing an unlicensed medicine you must:

- Be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy
- Take responsibility for prescribing the medicine and for overseeing the patient’s care, monitoring, and any follow up treatment, or ensure that arrangements are made for another suitable doctor to do so
- Make a clear, accurate and legible record of all medicines prescribed and, where you are not following common practice, your reasons for prescribing an unlicensed medicine.

71. You must give patients (or their parents or carers) sufficient information about the medicines you propose to prescribe to allow them to make an informed

decision.

72. Some medicines are routinely used outside the terms of their licence, for example in treating children. In emergencies or where there is no realistic alternative treatment and such information is likely to cause distress, it may not be practical or necessary to draw attention to the licence. In other cases, where prescribing unlicensed medicines is supported by authoritative clinical guidance, it may be sufficient to describe in general terms why the medicine is not licensed for the proposed use or patient population. You must always answer questions from patients (or their parents or carers) about medicines fully and honestly.”

With regard to prescribing drugs for the treatment of gender dysphoria, as described above:

- The gender specialist physician takes responsibility to assess the capacity of the patient to give meaningful informed consent to use such treatment, to explain its potential risks, benefits and limitations, to explain that the treatment is not approved for this indication and the implications thereof, and to obtain and document consent before making a recommendation to a GP to prescribe treatment for their patient;
- The gender specialist physician takes responsibility for overseeing the patient’s care in collaboration with the patient’s GP, and for their recommendation to the patient’s GP that the GP prescribe and monitor treatment;
- The gender specialist physician will provide the patient’s GP with the clear written guidance on prescribing and monitoring, be available to provide additional information on request, and answer GP questions regarding treatment and monitoring at reasonable notice;
- Prescribing of medicines for the unapproved application of treating gender dysphoria is supported by authoritative clinical guidance, specifically *Good practice guidelines for the assessment and treatment of adults with gender dysphoria* (RCPsych, October 2013; <http://www.rcpsych.ac.uk/usefulresources/publications/collegereports/cr/cr181.aspx>)
- Once a patient has completed their episode of care with a GIC, typically twelve months after completion of the last planned intervention, they will be discharged by the GIC. As almost all patients will need to continue taking hormone therapy for the rest of their lives, the GIC will, at the time of discharge, provide their GP with written guidance for ongoing prescribing and monitoring.

The decision on whether or not to initiate feminising or virilising endocrine therapy requires the highly specialised skills of a gender specialist physician, usually working within a GIC. The prescription of licensed products outside their approved indications, often but not always at the recommendation of a specialist provider, is not uncommon in general practice.

## Summary

GPs have an important role in the healthcare of people with atypical gender identity development, not only around the time of their transition to a social role and physical development that is congruent to their gender identity, but also for the rest of their lives when they no longer have a need for specialised gender identity services. GPs are urged to collaborate with GICs, working together to provide a seamless healthcare service for patients.

GPs are encouraged to cooperate with GICs in the prescription and monitoring of drug treatments for gender dysphoria, in compliance with the *Interim Gender Dysphoria Protocol and Service Guideline 2013/14* and the *Manual of Prescribed Specialised Services*.

## Action

In relation to individual patient care pathways GPs are encouraged to work with GICs to ensure Safe Management of care.

GPs are encouraged to provide the following components of the care pathway for people with atypical gender identity development:

- The prescription of hormone therapy, as recommended for their patients by GIC gender specialist physicians
- Patient safety monitoring procedures, working in co-operation with GICs;
- Provision of basic physical examinations (within the usual competences of GPs) and blood tests, as recommended by the GIC;
- GIC will assist GPs by providing specific, relevant information and support for prescribing and monitoring, including the interpretation of blood test results.

Once a patient has completed the care pathway and has been discharged by the GIC, GPs should offer them the usual range of primary healthcare services that are available to other patients.

## Further Information

Interim Gender Dysphoria Protocol and Service Guideline 2013/14:  
<http://www.england.nhs.uk/resources/spec-comm-resources/npc-crg/group-c/c05/>

Manual of Prescribed Specialised Services:  
<http://www.england.nhs.uk/wp-content/uploads/2012/12/pss-manual.pdf>

Good practice in prescribing and managing medicines and devices (2013):  
[http://www.gmc-uk.org/guidance/ethical\\_guidance/14327.asp](http://www.gmc-uk.org/guidance/ethical_guidance/14327.asp)

Good practice guidelines for the assessment and treatment of adults with gender dysphoria (RCPsych October 2013):  
<http://www.rcpsych.ac.uk/usefulresources/publications/collegereports/cr/cr181.aspx>



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