Lothian NHS Board

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Date: 29/01/2026
Our Ref: 10965
Enquiries to loth.freedomofinfomation@nhs.scot

Dear

FREEDOM OF INFORMATION – GENDER IDENTITY CLINIC PROTOCOLS

I write in response to your request for information in relation to protocols used by the Gender Identity Clinic in NHS Lothian.

Question:

Please provide copies of all protocols and guidelines used by the Chalmer Gender Identity Clinic for which WPATH SOC7 or WPATH SOC8 have been used as guidelines for the medical or surgical management of patients, including any shared care agreements with GPs.

Answer:

I have enclosed the protocols, guidelines and shared care agreements that the Chalmers Gender Identity Clinic have used as guidelines for the management of patients.

Included are the Gender Identity Healthcare Protocol for Scotland 2024, Endocrine and Fertility Preservation guidance, and both the feminising and masculinising Shared Care Agreements for NHS Lothian.

I hope the information provided helps with your request.

If you are unhappy with our response to your request, you do have the right to request us to review it. Your request should be made within 40 working days of receipt of this letter, and we will reply within 20 working days of receipt. If our decision is unchanged following a review and you remain dissatisfied with this, you then have the right to make a formal complaint to the Scottish Information Commissioner within 6 months of receipt of our review response. You can do this by using the Scottish Information Commissioner's Office online appeals service at https://www.foi.scot/appeal. If you remain dissatisfied with the Commissioner's response you then have the option to appeal to the Court of Session on a point of law.

If you require a review of our decision to be carried out, please write to the reviewer at the address at the top of this letter. The review will be undertaken by a Reviewer who was not involved in the original decision-making process.

FOI responses (subject to redaction of personal information) may appear on NHS Lothian's Freedom of Information website at: https://org.nhslothian.scot/FOI

Yours sincerely

ALISON MACDONALD
Executive Director of Nursing Midwifery and AHPs
Cc: Chief Executive

The Scottish Government
Directorate for Population Health

T: 0131 244 4000
E: directorforpopulationhealth@gov.scot

Scottish Government
Riaghaltas na h-Alba
gov.scot

Dear Colleague,

GENDER IDENTITY HEALTHCARE PROTOCOL FOR SCOTLAND

Summary

1. This letter provides Health Boards with the Gender Identity Healthcare Protocol for Scotland (GIHP). Please note that this supersedes CEL26(2012).

2. This updated protocol takes into account developments in terminology, best practice and service development within NHS Scotland for the provision of this care since publication of the 2012 Gender Reassignment Protocol for Scotland (GRP).

3. For the avoidance of doubt, this letter is not a direction under section 2 of the National Health Service (Scotland) Act 1978. The Scottish Government recognises that Health Boards remain under substantial financial and operational pressure across a wide range of clinical priorities. This protocol primarily codifies existing best practice already taking place across Scotland and in doing so seeks to support ongoing work to reduce regional variation in service provision.

4. The protocol should be used by Health Boards to inform local Standard Operating Procedures for how gender identity healthcare is accessed and provided. If a Health Board does not offer a gender identity clinic the protocol confirms that it still has a responsibility to its patients to ensure respective roles, responsibilities and referral and discharge routes are clear and formalised. It is acknowledged that many Health Boards that do not offer a gender identity clinic, but refer to a gender identity clinic in another Health Board, already have formalised agreements in place in the form of service level agreements.

Background

5. Following engagement with NHS National Services Scotland's National Gender Identity Clinical Network for Scotland (NGICNS) in 2021, the Scottish Government wrote to the

DL21(2024)

3 September 2024

Addressees

For action
NHS Chief Executives

For information
NHS Medical Directors
Chief Medical Officer
Deputy Chief Medical Officers

Enquiries to:

Gender Identity and Healthcare Access Policy Team

E-mail:
genderidentityhealth@gov.scot

NGICNS and NHS National Services Scotland (NSS), requesting they review and update the 2012 GRP. This was in recognition that the national protocol no longer fully reflected the strategic and clinical landscape within the NHS in Scotland for gender identity healthcare.

6. Following a series of working groups including clinical and third sector representative organisations, and targeted consultation, an initial draft of this document was submitted by NSS to the Scottish Government for consideration in late 2022. It was subsequently agreed with NSS that the Scottish Government would collaborate with them to take forward further work to finalise the new Protocol.

7. The GIHP sets out the clinical procedures and pathways governing **adult** gender identity healthcare services within NHS Scotland. This, alongside Healthcare Improvement Scotland Standards for Gender identity healthcare: Adults and Young People will help inform and support local Health Board Standard Operating Procedures to deliver consistent care.

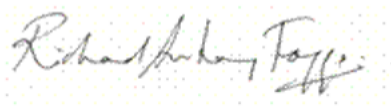
Children and Young People

8. Due to national work underway on how under-18s gender identity healthcare provision is commissioned most effectively for the NHS in Scotland, this protocol does not at this time address services for children and young people.

Action & Communication

9. Health Boards are asked to ensure that this updated protocol is fully communicated throughout each Board area to relevant staff for action, and patient groups.

Yours sincerely,



Richard Foggo
Director for Population Health

NHS Scotland Gender Identity Healthcare Protocol
September 2024

Contents

Executive Summary

1. This update of the 2012 Gender Reassignment Protocol for Scotland is part of wider national work to improve access to, and delivery of, gender identity healthcare within NHS Scotland. It is complemented by, and should be read in conjunction with, Healthcare Improvement Scotland Standards for Gender identity healthcare: Adults and Young People and the NHS Education for Scotland Transgender Knowledge and Skills Framework.

2. This protocol uses 'trans' as an umbrella term for people whose gender identity does not fully correspond with their recorded sex at birth. This includes, but is not limited to, trans women, trans men and non-binary people. For the purpose of this protocol it also includes people who are exploring their gender identity in relation to possible gender incongruence or dysphoria. A terminology guide is provided in **Annex A**.

3. The term 'gender identity healthcare' is used to encompass a range of non-surgical and surgical interventions available via NHS Scotland for people seeking medical support to manage distress caused by gender incongruence or gender dysphoria.

4. Gender incongruence is a clinical condition where there is a mismatch between a person's experienced gender and their sex recorded at birth. Gender dysphoria is clinically significant distress as a result of gender incongruence. This protocol will use the term gender dysphoria throughout.

5. In light of ongoing national work to commission gender identity healthcare services for young people this protocol does not address services for children and young people in detail.

The NHS Scotland Gender Identity Healthcare Protocol

6. The Referral, Assessment and Treatment Protocol is outlined in Figure 1 on page 8.

Interventions

7. The Protocol sets out locally and nationally provided non-surgical and surgical interventions via NHS Scotland as part of an adult's gender identity healthcare in **Annexes B** and **C**.

8. Referral to one of NHS Scotland's four gender identity clinics (GICs) is primarily made through a person's GP. Contact details for each GIC are provided in **Annex D**.

Adult Gender Identity Clinics

9. All adult GICs in NHS Scotland should operate using a multi-disciplinary team model. The clinical multi-disciplinary team should be supported by sufficient administrative staff. The wider care team may also include voluntary sector input.

Waiting list support and triage

10. Responsibility for care of a person waiting to access a GIC should be shared between the person's home Health Board and the GIC, and set out in a formalised agreement between the referring Health Board and GIC. This means:

    - GICs should have in place policies to ensure waiting lists to access the GIC are routinely validated;
    - if people waiting to access GICs are identified as likely benefitting from direct support from another clinical service e.g., Smoking Cessation or Mental Health services, processes should be in place to facilitate referral to relevant services in their home Health Board; and
    - all GIC waiting list communication should be consistent and in line with Health Board practices and policy for waiting list management, as per guidance issued to Health Boards within DL(2024)09.

Initial gender identity clinic assessment

11. Every initial assessment should involve the clinician and person identifying the possible reasons for the person's experience and challenges and, where this is related to gender dysphoria, explore possible options including:
    - carefully considering readiness to access gender identity healthcare; and
    - collaboratively developing a care plan that is based upon the person's needs.

12. In situations where an assessment proves more complex than anticipated, a multidisciplinary team approach should enable timely additional guidance to be sought to support shared decision making and identification of next steps.

Discharge and patient-initiated review

13. Local GIC pathways should prepare for discharge from its service, including:
    - a person being assessed as not being suitable to access gender identity healthcare or not requiring intervention, or discharge into ongoing care in the community following completion of treatment;
    - ensuring routes are available for a primary care provider to re-refer a person who had previously accessed NHS Scotland gender identity healthcare, if required; and
    - GICs should ensure they have processes and pathways in place to offer timely follow up to anyone who has previously accessed NHS gender identity healthcare and may wish to discuss potential options, including making changes to previous treatment they have requested or received.

Wider NHS role in the delivery of gender identity healthcare

14. All territorial Health Boards are expected to have, or put in place:
    - clear local arrangements which set out policy for referral, support and ongoing management of people seeking clinical support with gender dysphoria;
    - a formal agreement between the referring Health Board and GIC(s) their patients are referred to (e.g. a Service Level Agreement or part of regional planning);
    - this agreement should include clear roles and responsibilities regarding local provision of, and referral pathways to, non-surgical interventions
    - this agreement should include clear roles and responsibilities regarding surgical interventions locally available, and clear information on eligibility criteria;
    - confirmation of the local expenses policy for patients, as applicable, for treatment requiring travel outside their home Board;
    - a local policy on expectations of local primary care providers for their patient's ongoing care in the community e.g. provision of cross-sex hormone prescriptions and facilitating local monitoring blood tests as recommended by a GIC, and establishing responsibilities for the management of test results; and
    - adherence to all other legislation, national standards and guidance relevant to these services.

15. People should not be referred to GICs for issues unrelated to assessment and treatment for gender dysphoria, particularly when those who are not trans experiencing the same health issues would be expected to be routinely referred to other secondary care services.

The role of all NHS Scotland clinical staff

16. The delivery of care to people who are trans is expected to be delivered consistent with appropriate regulatory body guidance e.g. as issued by the General Medical Council or wider NHS Scotland standards regarding the provision of inclusive, person-centred care e.g. Health and Social Care Standards.

Independent Treatment

17. Where people choose to access an independent provider of gender identity healthcare, they are advised to only consider independent providers which are regulated by Healthcare Improvement Scotland, or its equivalent regulator elsewhere in UK nations.

18. As is the case across a wide range of health conditions and treatments, it is up to GP practices to decide whether they wish to enter into a Shared Care Agreement with a private provider. If GPs choose to provide an NHS prescription based on the recommendation of a private provider, routine monitoring should be provided on the same basis as other NHS prescriptions.

NHS Scotland Gender Identity Healthcare Protocol

Introduction

1. This document is an update of and replaces the 2012 Gender Reassignment Protocol for Scotland (CEL26(2012)).

2. This protocol is complemented by, and should be read in conjunction with, Healthcare Improvement Scotland Standards for Gender identity healthcare: Adults and Young People and the NHS Education for Scotland Transgender Knowledge and Skills Framework.

Review

3. It is expected this Protocol will require regular updates to remain current. As a result, Scottish Government Health Directorates will update, or commission an update, of this Protocol no later than December 2026.

Terminology

4. This protocol uses 'trans' as an umbrella term for people whose gender identity does not fully correspond with their recorded sex at birth. This includes, but is not limited to, trans women, trans men and non-binary people. For the purpose of this protocol it also includes people who are exploring their gender identity in relation to possible gender incongruence or dysphoria. An additional terminology guide is provided in **Annex A**.

5. This Protocol uses the term 'gender identity healthcare' to encompass a range of non-surgical and surgical interventions available via NHS Scotland for people seeking to access medical support to manage distress caused by gender incongruence, or gender dysphoria.

6. Gender incongruence is a clinical condition where there is a mismatch between a person's experienced gender and their sex recorded at birth. Gender dysphoria is clinically significant distress as a result of gender incongruence. This protocol will use the term gender dysphoria throughout.

Current delivery of gender identity healthcare

Adults

7. Gender identity clinics (GICs) in Scotland offer assessment and access to medical interventions in relation to gender dysphoria. At time of publication there are four GICs providing clinical assessment, treatment and specialist support to adults. These are based within four Health Boards:

- NHS Grampian
- NHS Greater Glasgow and Clyde
- NHS Highland
- NHS Lothian

Children and Young People

8. A separate service for children and young people – based within NHS Greater Glasgow and Clyde's Gender Service at Sandyford - accepts referrals from all Health Boards for young people up to the age of 18 years old.

9. At time of publication, underpinned by the Chief Medical Officer Directorate's Cass Review – Implications for Scotland: Findings Report, work is now underway via to develop sustainable service provision for young people in Scotland.

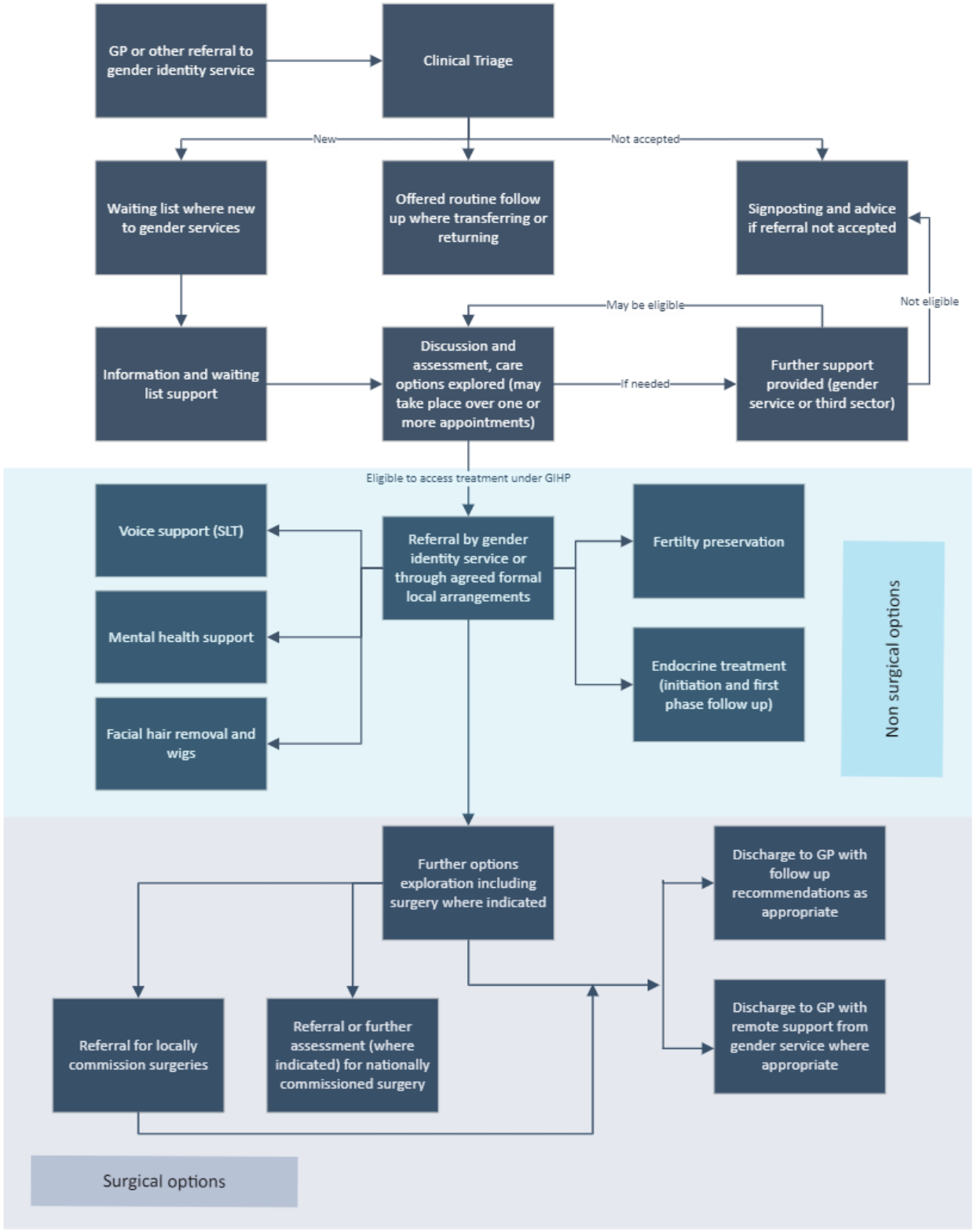
10. As a result, this protocol does not cover services for children and young people in detail. The Protocol will be reviewed in due course and, as appropriate, will incorporate provision of services for young people once national commissioning and planning processes are complete.

The NHS Scotland Gender Identity Healthcare Protocol

11. The Referral, Assessment and Treatment Protocol is outlined below in Figure 1.

12. Referral to one of NHS Scotland's four GICs is primarily made via a person's GP. This Protocol will be updated in the event there is any amendment to this. Contact details for each GIC are provided in **Annex D**.

FIGURE 1: NHS SCOTLAND GENDER IDENTITY HEALTHCARE PROTOCOL - REFERRAL, ASSESSMENT AND TREATMENT



Adult Gender Identity Clinics

13. All GICs in NHS Scotland should operate using a multi-disciplinary team (MDT) model. Staff working in or attached to GIC can include, but are not limited to, the following professions and specialties:

    - psychologists
    - psychiatrists
    - pharmacists
    - sexual health consultants
    - specialty nurses
    - specialty doctors
    - endocrinologists
    - GPs
    - primary care liaison e.g. link into local Community Treatment and Care (CTAC)

14. Every GIC should operate a regular MDT meeting. MDT meetings provide an opportunity for structured conversation about providing the best possible holistic care for people who have multiple and or complex needs. These meetings will involve a range of practitioners, each of whom brings their knowledge about the person and/or their area of specialist knowledge, to inform and jointly create a care plan. MDT meetings work best when they are regular, well structured and with a clear agenda, membership, roles and responsibilities.

15. Members of the MDT should have completed trauma informed training or complete it at the earliest opportunity.

16. MDTs may sometimes find it necessary to invite additional input from other clinics. GICs should consider providing support and expertise to other GICs when invited, in order to help promote nationally consistent care.

17. The clinical MDT should be supported by necessary administrative staff. The wider care team may also include voluntary sector input and support – for instance through commissioned support or community coordinator/care navigator roles.

18. Each adult GIC in Scotland differs in size and accepts referrals from a varying number of Health Boards, as well as its own. As is common with many secondary health services, local processes in each clinic will be flexible to accommodate differences in the size of service, local staffing contexts and associated governance.

Waiting list support and triage

19. Responsibility for care of a person waiting to access a GIC should be shared between the person's home Health Board and the GIC and set out in a formalised agreement between the referring Health Board and GIC. This means:

- GICs should have in place policies to ensure waiting lists to access the GIC are routinely validated;
- if people waiting to access GICs are identified as likely benefitting from direct support from another clinical service e.g., Smoking Cessation or Mental Health services, processes should be in place to facilitate referral to relevant services in their home Health Board; and
- all waiting list communication should be consistent and in line with broader Health Board practices and policy for waiting list management, as per guidance set out to Health Boards within DL(2024)09.

19. Dependent on individual need and circumstances some non-surgical interventions may be initiated prior to a first appointment at a GIC. For instance, it may be possible to self-refer to speech and language services or psychosocial support, dependent on the local policies of a person's home Health Board. GICs should take into account the local contexts of those accessing their services, wherever possible. This highlights the importance of ensuring a GIC and its referring Health Boards have jointly agreed waiting list policies in place.

Accessing a gender identity clinic - initial assessment

20. Every person's circumstance, goals and priorities for accessing a GIC will be unique to them. Every initial assessment will be needs led and include psychosocial assessment leading to the clinician and person identifying the possible reasons for the person's experience and challenges and, where this is related to gender dysphoria, explore possible options including:

    - carefully considering readiness to access gender identity healthcare; and
    - collaboratively develop a care plan that is based upon the person's needs

21. Clinicians carrying out needs led initial and ongoing assessments should be competent to identify a range of additional needs - for instance any relevant mental health concerns or neurodevelopmental needs, including where these impact accessibility. Where needs are identified and assessment for support is considered outside the competence of the initial assessor, or in situations where an assessment proves more complex than anticipated, processes should be in place to allow a multidisciplinary team approach and additional input from relevant colleagues to enable additional guidance to be sought and shared decision making to be reached safely with minimal delay.

22. As highlighted in Figure 1, initial assessment may result in a number of outcomes, including referral for treatment(s) or subsequent appointments within the GIC, as determined by the person's circumstances and clinical necessity.

23. Each GIC will have its own Standard Operating Procedures (SOPs) for clinical care. These will be informed by, and be consistent with, a range of local Health Board policies, this protocol, external resources such as guidance from professional bodies specific to the care being provided and National Standards produced by Healthcare Improvement Scotland. To assist ongoing development and review of such SOPs and to promote national consistency in this field, local initial assessment policies for accessing gender identity healthcare within NHS Scotland should:

    - agree with the person a pace of assessment that meets their needs, including those relating to accessibility;
    - discuss how possible treatment fits within the person's goals for managing gender dysphoria and their hopes or concerns;
    - promote a realistic understanding of expectations of positive and negative effects of any treatment, including impact on reproductive and sexual function;
    - identify and consider the impact of any significant co-existing mental health or physical concerns and offer signposting and support as appropriate;
    - explore fertility preservation options, where the proposed treatment has potential to affect reproductive function and seek referral where appropriate and requested;
    - assess whether the person is sufficiently informed and has capacity to give informed consent for the proposed treatment;
    - where a shared decision cannot be agreed, or there are concerns about capacity, identify additional psychosocial support or other interventions that could facilitate the person's readiness or ability to provide informed consent; seek input and guidance from a more experienced health professional if the complexity of co-existing conditions is outwith the scope of the health professional's competence;
    - where a shared decision cannot be agreed, and this is unrelated to capacity, identify support or interventions designed to work towards an agreed outcome or arrange for a further opinion if this is preferred by the person;
    - provide a pathway for a second opinion if the person wishes, and provide a pathway for reassessment at a later date; and
    - be clearly documented, in line with local Health Board policies.

24. Further example content which may inform initial assessment discussions is provided in **Annex E**.

25. Following assessment and a decision over next steps, and if determined that accessing gender identity healthcare would address clinical need, the term '*Meets the readiness criteria for and is eligible to access treatment under the NHS Scotland Protocol for Gender Identity Healthcare'* should be used in all communications.

26. ICD-11 HA60 'Gender Incongruence of Adolescence or Adulthood' may be recorded for coding purposes.

Gender Identity Healthcare – Treatments available via NHS Scotland

Non-Surgical interventions

27. The following non-surgical interventions may be provided via NHS Scotland as part of an adult's gender identity healthcare:
    - cross-sex hormone therapy
    - speech and language therapy
    - facial hair reduction via laser and/or electrolysis
    - wig prescription
    - occupational therapy
    - psychological therapies or interventions
    - psychosocial support (via NHS or via external organisations commissioned by the NHS)
    - group or individual peer-support
    - counselling for the individual/family/couple
    - help to explore gender expression and 'coming out'
    - help to develop social connections & peer support

28. Psychological therapies and interventions should be delivered in line with the Scottish Government's Psychological Therapies and Interventions Specification and Matrix.

29. Further information on non-surgical interventions is set out in **Annex B.**

Surgical interventions

30. Gender related surgery for adults is provided via one of two routes:

    - locally provided surgery
    - nationally commissioned surgery

31. Surgery that may currently be accessed nationally via NHS Scotland, delivered on a four nations basis by NHS England, for the purposes of treating gender dysphoria in adults are:

    - feminising and masculinising genital reassignment procedures
    - chest reconstruction for individuals recorded female at birth

Further information on both nationally commissioned surgery and surgery that may currently be provided locally within NHS Scotland Health Boards for the purposes of treating gender dysphoria in adults is set out in **Annex C**.

Discharge and patient initiated review

32. It is expected that local GIC policies which manage care take account of, and prepare for, discharge from its service. This may include considerations such as a person being assessed as not being suitable to access gender identity healthcare or not requiring intervention, or discharge into ongoing care in the community following completion of treatment.

33. However as highlighted in Figure 1, local policies should also reflect the ability of a primary care provider to re-refer a person who has previously accessed NHS Scotland gender identity healthcare, if required. This reflects the nature of the healthcare provided and may include a person wishing to explore further treatment options at their own pace. This could be described as a patient initiated review or follow-up.

Halting or reversal of NHS Scotland treatment

34. In a small number of cases, people who are either in the process of accessing gender identity healthcare or have previously accessed gender identity healthcare may decide to halt, or seek to reverse aspects of, their treatment. They should be appropriately supported. A person's individual reasons for stopping medical care or seeking its reversal will be highly personal and may be complex. For example:

    - they may no longer identify as trans or as a gender identity they previously identified with;
    - they may have experienced rejection from people close to them
    - they may have concerns about the impacts of medical interventions they have accessed to support a transition;
    - they may choose to pause the process, and some people who reverse aspects of their transition may decide to transition again at a later point; or
    - some trans people, especially older trans people, may reverse aspects of their transition because they are concerned that they may not receive appropriate care in care settings.

35. GICs should ensure they have processes and pathways in place within Standard Operating Procedures to support anyone who has previously accessed gender identity healthcare and may wish to discuss potential options, including making changes to previous treatment they have requested or received.

Wider NHS role in the delivery of gender identity healthcare

36. All territorial Health Boards are expected to have, or put in place:
    - clear local arrangements which set out the Board's policy for referral, support and ongoing management of people seeking clinical support with gender dysphoria;

- a formalised agreement between the referring Health Board and GIC(s) their patients are referred to. This may take the form of a Service Level Agreement or be incorporated into wider regional planning. To promote consistency, it is expected that such agreements will include an outline of the process by which a referral is made to a GIC; and requirements on a person's home Health Board to provide any necessary support for those waiting to access a GIC e.g., local referral into other services, as determined by need;
- this formalised agreement should include clear roles and responsibilities regarding local provision of, and referral pathways to, non-surgical interventions;
- this formalised agreement should include clear roles and responsibilities regarding clarity on what surgical interventions are available locally, with clear information on eligibility criteria;
- a local policy on expectations of local primary care providers for their patient's ongoing care in community e.g. provision of cross-sex hormone prescriptions and facilitating local monitoring blood tests as recommended by a GIC, and establishing responsibilities for the management of test results;
- confirmation of the local expenses policy for patients, as applicable, for treatment requiring travel outside their home Board; and
- adhere to all other legislation, national standards and guidance relevant to these services e.g. waiting times guidance as issued within DL(2024)09.

37. Primary care support for those accessing gender identity healthcare can include, but is not limited to, GPs, general practice nursing teams and board-employed Community Treatment and Care Services, pharmacists and sexual health services.

38. Trans people, including those accessing specialised gender identity healthcare, experience the same health issues as the general population and should be treated on the basis of need.

39. GICs within the NHS in Scotland only provide treatment and care directly relating to gender dysphoria. Trans people who present to primary care services with general health concerns and medical conditions should be reviewed and managed as per standard pathways, in line with professional guidance as set out by the Royal College of General Practitioners (RCGP) and the General Medical Council (GMC). Trans people should not be referred to GICs for issues unrelated to their gender identity, particularly when those who are not trans experiencing the same health issues would be expected to be routinely referred to other secondary care services. It is acknowledged however that primary care may need to seek specialist advice from a GIC regarding specific care or medication, unrelated to transition. In such specific instances GICs should have arrangements in place to support local primary care providers when this requirement arises.

40. To facilitate delivery of the above all Health Boards should work to ensure there is a formal agreement in place between their local primary care providers and GIC(s) that accept referrals. This agreement could reflect shared care or an enhanced service and should make clear the roles and responsibilities of the GIC, the home Health Board and its primary care providers in relation to a patient's gender identity healthcare and be implemented as policy. This includes any further local support for patients waiting to access, or discharged from, a GIC.

The role of all NHS Scotland clinical staff in the delivery of gender identity healthcare

41. Every person using NHS Scotland services should be able to access high-quality, person centred healthcare. The delivery of care to trans people is expected to be delivered consistent with appropriate regulatory body guidance e.g. as issued by the General Medical Council or wider NHS Scotland standards regarding the provision of inclusive, person centred care e.g. Health and Social Care Standards.

Further Considerations

42. The below subsections are provided as further context to inform local Health Board policies and their delivery of gender identity healthcare.

Independent Treatment

43. Where people choose to access an independent provider of gender identity healthcare they are advised to only consider independent providers which are regulated by Healthcare Improvement Scotland, or its equivalent regulator elsewhere in UK nations.

44. It is not recommended that people seek clinical treatment or care overseas where that would not have been offered by, or has had any involvement with, their local Health Board. Individuals should be made aware that standards of care delivery may not be as high in other countries as they are in Scotland or the wider UK. For example, NHS Inform provides information to people who may be considering surgery abroad without a NHS referral.

45. As is the case across a wide range of health conditions and treatments it is up to GP practices to decide whether they wish to enter into a Shared Care Agreement with a private provider. If GPs choose to provide an NHS prescription based on the recommendation of a private provider, routine monitoring should be provided on the same basis as other NHS prescriptions.

46. GPs may seek advice from their relevant GIC as to whether an assessment carried out by a private provider has been carried out by a clinician who it is understood meets the necessary competence, from a clinic that is registered with Healthcare Improvement Scotland or a similar UK regulator, whether the assessment carried out

is competent and whether proposed treatment and monitoring is consistent with published NHS Scotland endocrine guidance.

Self-Sourcing of Medication

47. There is evidence that some people may self-source cross-sex hormone medication from unregulated sources, either whilst on an gender identity clinic waiting list or otherwise. It is unlikely that this will be monitored by a regulated health professional.

48. Health Boards should ensure that local policies take account of this. Measures to support people in such circumstances, based upon the principles of harm reduction, are encouraged.

49. These may include activities to identify people who may be self-sourcing. Reasonable efforts should be made to balance the risk of inequitable consequence or treatment occurring to others waiting for or accessing gender identity healthcare against the need to reduce risk of harm to those self-sourcing.

Updating a Community Health Index Number (CHI)

50. Everyone in Scotland registered with a GP has a unique CHI number in which the penultimate digit is a binary gender marker (odd/even). Trans people can request that their CHI number is updated by asking their GP practice to update this.

51. Guidance for NHS staff responding to CHI change enquiries and information around screening can be found at: How to change patient details | National Services Scotland (nhs.scot).

Screening

52. Information about screening for trans people is available via NHS Inform. People accessing gender identity healthcare should be signposted to this information, especially to the different circumstances affecting those who changed their CHI number prior to June 2015.

Sexual Health

53. All services providing Sexual and Reproductive healthcare (SRH) to trans people should follow Healthcare Improvement Scotland Sexual Health Standards.

54. Trans people may have specific reproductive health care needs that change during the course of their gender identity healthcare. Reproductive healthcare needs will vary with the age when accessing trans healthcare and the healthcare interventions undertaken.

55. Gender identity healthcare clinicians should be competent in taking a sexual history for the purposes of counselling about expected effects prior to treatments and to establish any contraceptive requirement for testosterone users.

Individuals in custodial settings

56. Those in custody and prison who have been diagnosed with gender dysphoria, or who seek a clinical support while exploring their gender identity, should receive equitable healthcare and support compared to the general population, while considering the constraints of the prison or custody environment.

ANNEX A - Terminology

Term or Acronym	Definition
CHI Number (Community health index number)	Community Health Index (CHI) is a register of all patients in NHS Scotland and is used for health care purposes. The CHI number is ten numeric characters in length and uniquely identifies a person on this Index.
CTACS	Community Treatment and Care Services.
Gender dysphoria	This protocol uses ‘gender dysphoria’ to describe clinically significant distress related to gender incongruence. Treatments accessed under this protocol are intended to reduce or help manage gender dysphoria. Gender dysphoria may be more widely used by some trans people to describe feelings of discomfort or distress related to gender incongruence. Not all trans or gender diverse people experience gender dysphoria.
Gender identity	A person’s sense of having a particular gender; a way of describing the gender with which a person identifies such as man, woman or non-binary.
Gender incongruence	Describes the situation where a person’s gender is different to their sex recorded at birth. This term is preferable to terms used in the past like gender identity disorder and transsexualism. ‘Gender incongruence of adolescents or adults’ is defined in ICD-11 (International Statistical Classification of Diseases and Related Health Problems) as being characterised by a “marked and persistent incongruence between an individual´s experienced gender and the assigned sex, which often leads to a desire to ‘transition’, in order to live and be accepted as a person of the experienced gender, through hormonal treatment, surgery or other health care services to make the individual´s body align, as much as desired and to the extent possible, with the experienced gender” Clinically significant distress related to gender incongruence is known as gender dysphoria.

Term or Acronym	Definition
GIC	Gender Identity Clinic; specialist NHS gender identity services providing clinical assessment, treatment and specialist support.
GMC	General Medical Council – independent regulator for doctors in the UK.
ICD-11	International Classification of Diseases, published by World Health Organisation (WHO). Number 11 denotes current updated version.
NHS NSS	NHS National Services Scotland.
NHS NSS National Services Division (NSD)	National Services Division, part of NHS NSS. Their activities include planning, commissioning and coordinating high-quality, person-centred specialist services, networks and screening programmes in Scotland.
Independent healthcare/independent providers	Defined in the National Health Service (Scotland) Act 1978 as clinics that are not part of a hospital and from which a medical practitioner, dental practitioner, registered nurse, registered midwife or dental care professional (clinical dental technician, dental hygienist, dental nurse, dental technician, dental therapist, orthodontic therapist). provides a service, which is not part of the National Health Service. The term 'service' includes consultations, investigations and treatments.
Multi-disciplinary Team	A multi-disciplinary team (MDT) is a group of health and care staff who are members of different organisations and professions (such as GPs, nurses, psychiatrist, etc.) who work together with an aim to deliver person-centred care and support for each individual patient and service user.
NGICNS - National Gender Identity Clinical Network for Scotland	The National Gender Identity Clinical Network for Scotland (NGICNS), hosted by NSS, was established to oversee the implementation of 2012 Gender Reassignment Protocol across Scotland. It aims to work with gender identity clinics, gender reassignment surgical providers, primary care, patient and third sector representation to achieve timely, coordinated, service provision and equitable access to planned gender identity clinical services across Scotland.

Term or Acronym	Definition
Non-binary	Someone who does not identify as a man or a woman or who identifies as both or as something else completely. A non-binary person may or may not identify as trans.
Person-centred care	Care focused on the needs of the individual accessing service.
Primary care	This refers to an individual's first point of contact with NHS Scotland, usually their GP.
RCGP	Royal College of General Practitioners - professional membership body for GPs at all stages of their career in the UK.
RCSLT	Royal College of Speech and Language Therapists - professional body for people working in or studying speech and language therapy in the UK.
Service Level Agreement	A written agreement which sets out what services will be provided by Service provider, and how and when these will be provided, the financial arrangements for the provision of agreed services, and any associated responsibilities.
Trans people	An umbrella term for people whose gender identity does not fully correspond with their sex recorded at birth. This includes, but is not limited to, trans men, trans women and non-binary people.
Transition	Often used to describe the process a trans person goes through from being known as one gender to being known as another. This transition may be social, such as involving a change of name and presentation, and it may involve medical intervention in the form of hormone replacement therapy and/or surgery. This term, however, can mean different things to different people. Some people prefer the term gender reassignment.

ANNEX B - Non-Surgical Interventions

Speech and Language Therapy

1. Speech and language therapy services will be provided by a person's home Health Board and may be delivered via a range of modalities including face to face, video consultation, group and individual. Although referral pathways to speech and language services may vary by Health Board, all territorial Health Boards should have established referral, assessment and triage options for speech and language therapy for trans people if required.

2. Where available, referrals to speech and language services may be made:

    - as a self-referral by the person, where local processes are available, when accessing a gender identity clinic or waiting to access a gender identity clinic, or in need of no other support than speech and language therapy;
    - to local speech and language services by a GP; or
    - by a clinician at a gender identity clinic.

3. Voice and communication specialists working with trans people should develop skills for understanding gender diversity using the Royal College of Speech and Language Therapists (RCSLT) Trans and gender-diverse voice & communication therapy competency framework and be part of the RCSLT clinical excellence network.

Facial hair removal

4. Available guidance on the provision of Facial Hair Removal for Transgender Patients should be followed by Health Boards.

Wig provision

5. Available guidance on the provision of wigs should be followed.

6. To reduce unnecessary referral delay and clinical time within dermatology and to facilitate equity of access, Health Boards should put in place pathways to accept referrals directly to the wig service from the GIC. The referring clinician will complete the wig referral form with all relevant information.

Endocrine intervention

7. Clinicians involved in the care and management of trans people and associated cross-sex hormone prescription making recommendations about, or prescribing cross-sex hormones or other gender identity related endocrine treatments, should take account of the National Gender Identity Clinical Network for Scotland (NGICNS) July 2022 Endocrine and Fertility Preservation Guidance .

8. This guidance has been updated and replaces the previous NGICNS guidance on ‘Endocrine Management of Adult Transgender Patients’, first published 11 August 2015 and revised 7 July 2018.

Gender identity specific psychosocial support

9. Gender identity specific psychosocial support should aim to be accessible as an option throughout gender identity healthcare. It may include the individual, a couple or family, groups and should:

    - be accessible throughout gender identity healthcare provision;
    - take a tiered approach;
    - reflect individual goals, needs, requests;
    - take a non-directive support to explore gender identity, role, and expression;
    - work to address the negative impact of gender dysphoria and stigma on mental health;
    - work to alleviate internalised transphobia;
    - work to enhance social and peer support;
    - work to improve body image;
    - promote resilience; and
    - not impede access to other aspects of gender identity healthcare.

10. If evidence based psychological therapies and interventions are required, this should be delivered in line with the Scottish Government’s Psychological Therapies and Interventions Specification and Matrix.

ANNEX C - Surgical Interventions

Surgical interventions available via NHS Scotland

1. Reassignment surgery for adults is provided via one of two routes:

    - locally provided surgery
    - nationally commissioned surgery

2. Information on each surgical route is set out below. Health Boards should note that people may access one or both routes, dependent on individual need and in consultation with their clinical team.

3. People considering surgery should be offered appropriate space, support and information to fully explore their options. This provision should be in place for anyone considering one of these procedures and accessible regardless of whether they are actively seeking or awaiting referral. Clinicians supporting people with these decisions must have appropriate knowledge, skill and competence and ensure that:

    - people considering surgical interventions are offered support and information to fully explore their options; and
    - referrals for surgical intervention are only initiated under the governance of an NHS Scotland gender identity clinic.

Locally provided surgery

4. Surgery that may currently be provided locally within NHS Scotland for the purposes of treating gender dysphoria in adults are:

    - breast augmentation
    - body contouring
    - chondrolaryngoplasty
    - facial feminising procedures
    - hysterectomy
    - oophorectomy
    - orchidectomy

5. The above surgical interventions do not require NHS NSS National Services Division approval. Decisions on their availability are instead made by a person's local Health Board.

6. Health Boards should ensure they have clear documentation on what is available to their patients and have local policies in place regarding access to them. This will require engagement with local clinical teams and the referring GICs to put in place appropriate policies.

7. Local policies may consider it reasonable that referrals to locally provided surgery can be made on the basis of clinical recommendation from an NHS Scotland gender identity clinic, where the referring clinician and person are in agreement that the surgery is indicated, be of benefit to the person and the circumstances relating to the decision are not considered complex. Where a further opinion is required, the referring clinician should facilitate this with minimal delay, unless delay is requested by the person seeking surgery.

Nationally commissioned surgery

8. Nationally commissioned surgery includes:

    - feminising and masculinising genital reassignment procedures
    - chest reconstruction for people recorded female at birth

9. Referrals are authorised by NHS National Services Scotland on behalf of all Health Boards and are carried out under a four nations contract managed by NHS England. The NHS Gender Identity Services for Adults (Surgical Interventions) specification makes clear how referrals for these services function.

10. People can be referred for nationally commissioned surgery via their gender identity clinic, following consultation with their clinical team and meeting required governance arrangements to access surgery via the four nations contract or otherwise agreed by NHS National Services Scotland.

11. Health Boards should note that a request may be made by the person's surgical team for donor site hair removal. This should be provided via the person's local Health Board.

Post-surgical care

12. Surgical providers are responsible for immediate post operative after-care and generally thereafter for the first 12 months post-surgery.

13. An unscheduled aftercare pathway should be available for surgical revisions sought after the original episode of care is completed.

14. Access to this pathway, managed on a similar basis to other referrals via NHS National Services Scotland, is made available via the person's NHS Scotland gender identity clinic.

Further action

15. As part of consideration of this protocol, NHS NSS and lead clinicians in this field recognised further work is required – at a national level – to deliver equitable access for what is currently locally commissioned surgery.

Scottish Government will therefore convene a short-life working group in 2025 to:

- review availability of surgery delivered by local Health Boards within NHS Scotland which are not nationally commissioned;
- provide a recommendation on what further surgery, if any, should be provided via NHS Scotland;
- provide a recommendation on whether any currently available surgery should no longer be made available via NHS Scotland;
- provide a recommendation on how such surgery should be delivered e.g. locally, regionally or nationally; and
- consider if the 2019 Exceptional Referral Protocol should be updated in order to apply to this surgical provision.

ANNEX D - Gender Identity Clinic Contact Details

Gender Identity Clinic	Accepts referrals from	Contact details
Sandyford Adult Gender Service	• NHS Ayrshire & Arran • NHS Dumfries & Galloway • NHS Forth Valley • NHS Greater Glasgow & Clyde • NHS Highland[1] • NHS Lanarkshire • NHS Tayside • NHS Western Isles	Sandyford Clinic Glasgow 6 Sandyford Place Glasgow G3 7NB **Tel**: 0141 211 8130 **Email**: adultgender.sandyford@ggc.scot.nhs.uk **Website**: https://www.sandyford.scot/sexual-health-services/gender-service-at-sandyford/
The Chalmers Centre Gender Identity Clinic	• NHS Borders • NHS Fife • NHS Lothian	Chalmers Sexual Health Centre 2A Chalmers Street Edinburgh EH3 9ES **Tel**: 0131 536 1570 **Website**: https://www.lothiansexualhealth.scot/gender-identity-clinic/
Highland Gender Identity Clinic	• NHS Highland	Highland Gender Identity Clinic Highland Sexual Health Royal Northern Infirmary Ness Walk Inverness IV3 5SF **Tel**: 01463 888300 **Email**: nhsh.gicadmin@nhs.scot **Website**: https://highlandsexualhealth.co.uk/gender-identity
Grampian Gender Identity Clinic	• NHS Grampian • NHS Orkney • NHS Shetland	Elmwood Hospital Ashgrove Road Aberdeen AB25 3BW **Tel**: 01224 557 170 **Email**: gram.gic@nhs.scot

[1] In specific instances related to geographical location – for instance for people based in Argyll and Bute.

ANNEX E - Assessment for Adults

1. The key principles of delivery of gender identity healthcare are that care delivered should:
   - be holistic, person-centred and needs-led;
   - work with the spectrum of gender diversity and identity;
   - allow people to present authentically;
   - provide equitable access regardless of location in Scotland;
   - provide access regardless of ethnicity, age, race, neurodiversity, ability, physical health status or other intersection; and
   - foster collaboration and cooperation of different clinicians to deliver holistic, person-centred care.

Example Content for Adult Assessment

2. A basic psychosocial assessment is recommended for adults that includes a narrative of gender history, transition progress and expectations. It should be adapted to the individualised context of the person and to the intervention proposed. At all stages this is a collaborative process between the trans person and their clinician with shared decision making.

3. This example content can be adapted as appropriate.

Introduction

Expectations
- person's expectations from the engagement and proposed intervention
- understanding of existing experience and knowledge
- agree themes for assessment

Gender
- current gender identity and expression
- gender history, development and experience
- timeline of gender identity development
- experience and progress of social transition
- impact of relevant physical changes
- experience of gender dysphoria
- establish and agree presence of gender incongruence

Social
- discuss accommodation, family/friends, education, work as relevant
- identify social support and wider community networks
- impact of wider social and cultural context
- consider social impact of further transition and discuss potential barriers

Mental Health
- explain basis for discussing mental health and reassure that this is a supportive element of the process

- mental health and neurodevelopmental history (conditions diagnosed or suspected)
- understanding of any previous formal contact with mental health or psychological services
- taking a trauma-informed approach, consider the impact of any previous trauma or negative experience and its relationship to the assessment and any proposed treatment
- discuss risk including suicidal thoughts/actions and self harm
- explore any current concerns and identify support as appropriate
- the key principles of gender specific psychosocial support are given in **Annex B**

Medical

- medical history
- any current conditions or waiting for treatment
- medications
- smoking and other substances
- family history especially blood clots, cardiovascular disease or cancer

Sexual Health & Fertility

- sensitively explore sexual health history
- offer sexual health testing where indicated and requested
- explore impact of any proposed intervention on sexual function
- discuss contraception where indicated
- discuss thoughts about future family and explain options for fertility preservation where eligible
- offer referral for fertility preservation where requested

Reflection and Consent

- provide verbal and written information prior to decision making about the proposed intervention
- ensure that there is an effective understanding of any proposed intervention including a full discussion about benefit and risk
- clearly identify elements of any intervention that are irreversible and ensure there is sufficient space for this to be explored
- where there is uncertainty or concern about capacity access timely support from a suitable multidisciplinary team.
- confirm the outcome of the assessment with the person verbally and in writing

NGICNS
National Gender Identity Clinical Network for Scotland

NHS National Services Scotland

Endocrine and Fertility Preservation guidance

Contents

Introduction

This guidance relates to the provision of feminising and masculinising gender affirming hormone treatment for transgender, non binary and gender diverse (TGD) people. It updates and replaces the previous NGICNS guidance on 'Endocrine Management of Adult Transgender Patients', first published 11 August 2015 and revised 7 July 2016 and 18 October 2018.

It has been structured with three main sections; masculinising gender affirming treatment, feminising gender affirming treatment and fertility preservation, followed by appendices covering medical conditions and endocrine treatments, off licence prescribing, and Gamete storage for use by 3rd party reproduction.

The guidance development group convened by National Services Division (listed in an appendix 6) had diverse professional and lived experience. While previous versions of this and other guidelines as well as primary research were used in developing this document, it is recognised that the evidence base remains incomplete and that there is variation in acceptable practice, which will therefore evolve over time. In this document we have aimed to outline what is currently considered best practice for safe and effective care as applicable within NHS Scotland for endocrine management and fertility preservation in this field.

1. Masculinising gender affirming hormone treatment

This guidance makes no assumptions about an individual's gender identity but provides information with regard to masculinising hormone treatment.

This guidance relates to people originally assigned female at birth, wishing masculinising hormone treatment who are aged 16 years and over and have completed puberty.

Masculinisation is achieved by commencing testosterone treatment.

1.1. Baseline assessment

The aim of the baseline assessment is for the person who is starting testosterone to have a discussion with an appropriately experienced professional about the risks and benefits of starting testosterone treatment, to enable an informed choice to be made about starting testosterone treatment.

The baseline assessment should cover the following areas:

1) Medical review and family history
2) Likely effects of commencing testosterone treatment
3) Potential risks of starting testosterone treatment
4) Advice on the impact on fertility, contraception and pregnancy
5) Treatment options
6) Agreeing a starting dose and titration regime
7) Maintenance doses
8) Ongoing monitoring requirements.
9) Consent

1.2. Medical review and family history

There are almost no absolute contraindications to starting testosterone treatment. There needs to be a review of medical and family history so the person considering treatment can understand the potential risks and ongoing monitoring required if testosterone treatment is started.

- Medical and family history are taken. Conditions that are of particular relevance regarding testosterone treatment are below highlighted below, more details are available in Appendix 1

    - Cardiovascular disease
    - Cardiovascular risk (Assess cardiovascular risk using a recognised tool e.g. qrisk3 or ASSIGN)
    - Polycythaemia
    - Hypertension
    - Diabetes
    - Liver disease
    - Breast disease
    - Abnormal vaginal or menstrual bleeding, and prolonged amenorrhoea

- Check Baseline FBC and lipid profile.
- Baseline liver function
- Baseline hormonal profile particularly if history of amenorrhea/irregular periods (LH, FSH, estradiol, testosterone, prolactin).
- BMI: high BMI is not a contraindication for hormone treatment. However, people with high BMI should be should be counselled re. the additional risk of a higher BMI, offered weight-loss assistance and informed clearly that there are BMI limits for most NHS funded surgical procedures

1.3. Likely effects of commencing testosterone treatment

Table 1 shows the effects and expected time course of testosterone treatment.

These changes should be discussed with the person considering starting testosterone treatment. Testosterone treatment has a systemic (whole body) effect, so it is not possible to be selective about which effects occur and which do not.

It should be advised that the degree of change is highly variable for person to person, as can be seen in the variation across the general population e.g. amount of facial body hair / body build. These differences are dependent on not just testosterone levels but other factors such as genetics, exercise and build.

Androgen dependant balding or male pattern hair loss is genetically determined. This genetic potential will be revealed by starting testosterone treatment. There are

limited effective treatments for male pattern balding. Any advice and treatments would be as per the general population.

It should be advised that some of these changes (notably voice change and facial hair) are likely to be permanent and will not completely resolve on stopping hormone treatment.

Periods will usually restart if testosterone is stopped (although menopause will occur at the normal age).

Testosterone will not alter height, once final height has been achieved.

Aggression is not usually seen in people given physiological (normal range) testosterone treatment. Aggression can be seen in people taking excessive testosterone treatment but this is not the aim of masculinising hormone treatment. Mood and other aspects of mental health usually improve as the effects of testosterone develop.

Table 1

Effect	Expected Onset	Expected Maximum Effect
Skin oiliness/acne	1-6 months	1-2 years
Deepened voice	3-12 months	1-2 years
Facial/body hair growth	3-6 months	3-5years
Scalp hair loss	>12 months	variable
Increased muscle mass/strength	6-12 months	2-5 years
Body fat redistribution	3-6 months	2-5 years
Cessation of menses	2-6 months	n/a
Clitoral Enlargement	3-6 months	1-2 years
Vaginal atrophy	3-6 months	1-2 years

Source: Adapted from Hembree et al (2009). Effects also dependant on genetics, exercise, build.

1.4. Potential risks of starting testosterone treatment

See Appendix 1: Medical conditions and testosterone for full details

Testosterone treatment has been shown to increase cardiovascular risk in some studies.

Testosterone treatment can also be associated with an increased haematocrit which will increase cardiovascular risk and may worsen cardiovascular disease. Risk of polycythaemia can be reduced by addressing other risk factors such as smoking and obesity.

Men have an increased risk of diabetes. Screening and treatment should be as general population

Oral testosterone is not recommended as it is associated with impaired liver function and liver tumours. There is no evidence that transdermal or IM preparations affect liver function/ cause liver tumours. Impaired liver function/liver disease should be investigated and managed as per general population.

Testosterone has been associated with male breast cancer but there is no evidence of increased risk of breast cancer in this group. For people with breast tissue breast screening should be performed as per guidelines.

Testosterone treatment will usually cause cessation of periods. There is currently insufficient evidence to suggest routine ultrasound scanning to assess endometrial thickness for people on testosterone, however people with new or abnormal bleeding on testosterone should be investigated as per standard guidelines.

1.5. Advice on the impact on fertility, contraception and pregnancy

Fertility

People should be made aware that hormonal preparations impair fertility. Prior to starting testosterone, future fertility options need to be explored. Should the person wish to preserve their fertility then referral to the local fertility clinic or fertility preservation team should be made, ideally prior to starting full dose testosterone treatment. Please see Fertility Preservation section for more details.

Contraception

Although most people on full dose testosterone treatment will not have periods, testosterone is not a reliable contraceptive and if required, contraception should be used. People can use their preferred method but oestrogen-containing contraceptives are less popular, and concomitant use with testosterone should be avoided because of the thrombosis risk. Progestogen-only contraceptives or intrauterine methods (IUS or IUD) may be more acceptable.

Pregnancy

Testosterone treatment needs to be stopped prior to conception and should not be restarted until after delivery.

There is a risk of foetal abnormality when a pregnancy is conceived while on testosterone treatment. Testosterone needs to be stopped prior to conception. The time required for testosterone levels to reduce to pre-treatment levels varies widely depending on the preparation. Expert advice should be sought in advance of conception, or in the event of unintended pregnancy.

Testosterone can usually be restarted soon after delivery, depending on the individual's thrombosis risk and decision/options regarding breast feeding.

1.6. Treatment options

Masculinising hormone treatment is achieved by commencing testosterone.

Recommended testosterone preparations are either transdermal preparations or intramuscular (IM) injections.

Oral testosterone is not recommended due to poor bioavailability resulting in low blood levels, and adverse effects on the liver.

Most testosterone preparations, with the exception of Sustanon, do not have a marketing authorisation for use as a gender affirming treatment See Appendix 2 for guidance on prescribing medication "off licence", i.e. outside the conditions of the marketing authorisation.

1.7. Agreeing a starting dose and titration regime

Gradual introduction of testosterone is recommended. This is usually achieved with transdermal preparations such as gels. Different brands of gel have different concentrations and care should be taken when switching between brands. **Testosterone gel should therefore be prescribed by brand name.**

Table 2: recommended starting doses/titration and usual maintenance doses for some testosterone gels.

Brand	Type	Concentration	Amount per metered dose or sachet/tube	Starting dose	Titration	Usual maintenance dose
Tostran ®	Pump	20mg/g	10mg in 0.5g press	2 presses (20mg)	Increase by 1 press a month	4-6 presses
Testogel ® pump	Pump	16.2mg/g	20.25mg in 1.25g press	1 press (20.25mg)	Increase to 2 presses after 2 months	2-3 presses
Testogel ® sachet*	Sachet	16.2mg/g	40.5mg per 2.5g sachet	½ sachet (20.25mg)/day or one sachet 40.25mg) on alternate days	Increase to 1 sachet daily after 2 months	1 sachet
Testim®	Tube	10mg/g	50mg per 5g tube	½ tube (25mg)/day or one sachet 50mg) on alternate days	Increase to 1 tube daily after 2 months	1 tube
Testavan®	Pump	20mg/g	23mg in 1.15g press	1 press (23mg)	Increase to 2 presses after 2 months	2-3 presses

* Testogel® 50mg sachet discontinued

If transdermal gel is not suitable, an alternative is Sustanon (a mixture of testosterone decanoate, isocaproate, phenylpropionate and propionate). As Sustanon contains arachnis oil it should be avoided if there is a history of peanut or soya allergy. Use of testosterone enantate (starting dose 125mg i.e. 3 weekly) is appropriate if Sustanon is not suitable. It is shorter acting and, although generically named, significantly more expensive than Sustanon. Sustanon and testosterone enantate can be injected into the vastus lateralis (thigh) muscle so can be self-administered after appropriate instruction.

Testosterone undecanoate (Nebido) is a long acting testosterone and is therefore not routinely recommended as an initial therapy. It can be considered if other options are not appropriate, however, the long duration with rapid onset of adult male testosterone levels should be discussed with the individual. Nebido contains castor oil. It is only suitable for injection into the gluteal (buttock) muscle because of its 4ml volume. It should be injected slowly over 2 minutes by an appropriately qualified person.

Once established on testosterone, menses will usually stop. If there is a desire to stop periods more quickly GnRH analogues can be prescribed. These are not usually not required in the long term and are typically stopped after 6 months but can be continued longer if required. Options include Leuprorelin/Triptorelin 3.75mg 4 weekly, 11.25mg 12 weekly or 22.5mg six monthly by IM injection, Goserelin 3.6mg implant subcutaneously 4 weekly or 10.8 mg implant 12 weekly.

1.8. Maintenance doses

Testosterone gel can be continued long term, alternatively, testosterone undecanoate (Nebido) can be considered after 4-6 months of testosterone treatment.

Testosterone undecanoate is usually started as follows:

Starting doses:
1g week 0,
1g week 6,
1g week 18 (ie 12 weeks after 2nd injection) then continued every 12-16 weeks.

Trough testosterone and FBC should be checked prior to 4th injection, with the interval between injections adjusted to maintain trough testosterone no greater than mid age adjusted male range, and haematocrit in normal male range. Loading intervals can be adjusted if there are concerns about haematocrit, e.g. week 0, 2nd week 8, third week 20.

1.9. Ongoing monitoring requirements

Testosterone levels and haematocrit should be monitored every 4-6 months while dose is titrated and then annually once the individual is established on a dose.

Testosterone levels

Testosterone levels should be checked:

- 2-6h after gel application
- Just prior to injection (trough level)

In people on testosterone supplementation there is no need for blood samples to be taken while fasted or early morning.

Local age adjusted male ranges should be used when measuring testosterone levels.

Target Testosterone levels:

- 2-6h after gel: no higher than the age adjusted male range
- For trough levels prior to IM injection: lower to mid age adjusted range.

Target testosterone levels should be clearly communicated by GIC to primary care. Beware of spuriously high levels from contamination of the injection site with gel. Consider repeating the test, especially if the haematocrit level does not correspond.

Effects of testosterone treatment are dependent on other factors in addition to achieved testosterone levels e.g. genetics/body size and aiming for higher or lower testosterone levels may not alter the achieved effects.

Haematocrit

Aim for haematocrit ideally less than 0.5 but within the normal male range. The dose of testosterone should be reduced if haematocrit is elevated. Changing from injectable testosterone preparations to transdermal may be beneficial. **Seek urgent advice if haematocrit >0.6**. See Appendix1 for more details

1.10. Consent

If the person wishes to commence testosterone consent should be obtained using information in the consent form and this decision documented in medical records and shared with GP.

1.11. Ongoing care

1) Annual blood monitoring as above for testosterone levels and haematocrit.

2) Screening - more details are contained in the monitoring and screening section.

   - Cervical screening should continue as for female guidelines if cervical tissue is present, however, sensitive discussion of this should take into account the patient's dysphoria
   - Breast screening should also follow female guidelines if mastectomy/chest reconstruction has not been performed (surgeon should confirm if all breast tissue has been removed)

   - Cardiovascular risk should be assessed as per the general population. Risk calculations should use male gender. Cardiovascular risk factors should be treated as per the general population. Trans men will be invited for abdominal aortic aneurysm (AAA) screening at age 65 years if they are recorded as male in their NHS record. They have a lower risk of AAA than natal males but they can decide whether they wish to take part in AAA screening.

Further information on NHS Scotland's screening programmes can be found here

3) Ongoing medical care

Testosterone treatment will not alter management of other health conditions and people should be investigated and referred through standard pathways. If there are concerns about the ongoing safety of continuing testosterone refer back to local GIC or endocrine services.

4) Vaginal Atrophy

Vaginal atrophy can occur with testosterone therapy. If required this can be managed with topical vaginal oestrogen. Systemic (whole body effects) are minimised by using the lowest effective dose to control symptoms. Treatment is continued for as long as needed to relieve symptoms, for example vaginal pessaries 10micrograms daily for 2 weeks then reduced to 10micrograms twice weekly.

5) Considerations later in life

Although a number of studies have shown a fall in testosterone levels with age, this is most likely due to high prevalence of other conditions such as obesity and long term health conditions, rather than a normal physiological response. This age related fall is not seen in healthy populations. Testosterone treatment can therefore be continued lifelong if desired. Dose may need to be adjusted depending on other health conditions.

1.12. Stopping testosterone treatment

Any individual making the decision to stop testosterone treatment should be adequately informed of the risks and benefits. Stopping treatment completely is rarely required purely on medical grounds. An individual may decide that the benefits do not outweigh the potential risk or they may feel that the desired effects have been achieved. This is absolutely the person's choice and options should be discussed with an appropriately experienced professional.

Stopping treatment may lead to deterioration in mental health. Irrespective of the reason for stopping, individuals should be offered review while they adjust, and psychological support if required.

Testosterone treatment should be stopped temporarily during pregnancy.

The long term effects of stopping testosterone will depend on whether gender reassignment surgery (GRS) has been performed.

No Gender Reassignment Surgery

Stopping testosterone in people who have not had GRS will usually result in a return to menstrual cycles and return pretreatment levels of oestrogen and progesterone as testosterone levels fall. In people on longer acting testosterone treatment such as testosterone undecanoate (Nebido) this may take 6 months. In people who are post-menopausal oestrogen levels will remain low. People may experience symptoms of sex hormone deficiency

such as flushing and loss of libido. Low dose sex hormone in the form of either oestradiol or testosterone can be used temporarily to relieve symptoms but may delay return of endogenous hormone levels.

GRS with oophorectomy

If GRS including oophorectomy has been performed stopping testosterone will result in deficiency of sex hormones. Long periods of sex hormone deficiency can be associated with long term health effects notably osteoporosis. Sex hormone (oestrogen usually or low dose testosterone) replacement would usually be recommended up to the natural age of menopause (usually around 50-55years) to protect bone health.

2. Feminising gender affirming hormone treatment

2.1. Introduction

This guidance makes no assumptions about an individual's gender identity but provides information with regard to feminising hormone treatment.

This guidance relates to people originally assigned male at birth wishing feminising hormone treatment who are over the age of 16 and who have completed puberty.

Feminisation is achieved by commencing oestrogen and, if needed, use of GnRH analogues for suppression of the reproductive axis.

2.2. Baseline assessment

The aim of the baseline assessment is for the person who is starting feminising gender affirming hormone treatment to have a discussion with an appropriately experienced professional about the risks and benefits of starting endocrine treatment. By the end of the review they should be able to make an informed choice about starting endocrine treatment.

The baseline assessment should cover the following areas:

1. Medical review and family history
2. Higher risk groups including individuals over the age of 40
3. Likely effects of commencing hormone treatment
4. Potential risks of starting hormone treatment
5. Advice re. the impact on fertility and contraception
6. Treatment options
7. Agreeing a starting dose and titration regime
8. Maintenance doses
9. Ongoing monitoring requirements
10. Consent

2.3. Medical review and family history

There are almost no absolute contraindications to starting feminising gender affirming hormone treatment. There needs to be a review of medical and family history so there can be a tailored discussion so the person considering hormone treatment can understand the potential risks and ongoing monitoring required if hormone treatment is started.

- Medical and family history are taken. Conditions that are of particular relevance regarding hormone treatment are (see **Appendix 3**):
    - Cardiovascular disease
    - Cardiovascular risk (Assess cardiovascular risk using a recognised tool e.g. qrisk3 or ASSIGN)
    - Prostate disease
    - Hypertension
    - Diabetes
    - Liver disease
    - Breast disease
    - Migraine
    - Thromboembolic disease

- Baseline hormonal profile (LH, FSH, estradiol, testosterone, prolactin).
- Where clinically indicated check:
    - Baseline FBC, lipid profile and HbA1c.
    - BP
    - BMI: high BMI is not a contraindication for hormone treatment. However, people with high BMI should be should be counselled re the additional risk with a higher BMI (in particular relating to the risk of VTE), offered weight-loss assistance and clearly informed there are BMI limits for some surgery

2.4. Higher risk groups including individuals over the age of 40

For individuals starting hormone treatment after the age of 40 or with additional risk factors or QRISK3 score >5-10% careful discussion about risks and benefits is needed including realistic discussion about the physical changes that can be expected with starting feminising hormone treatment at this age. Transdermal preparations are recommended for individuals over 40 and in patients with cardiovascular risk factors, high BMI, liver disease.

2.5. Likely effects of commencing feminising gender affirming hormone treatment

Table 3 shows the effects and expected time course of feminising gender affirming hormones.

These changes should be discussed with the person considering starting hormone treatment. Hormone treatment has a systemic (whole body) effect so it is not possible to be selective about which effects occur and which do not.

It should be advised that the degree of change is highly variable from person to person, as can be seen in the variation seen across the general population, for example in breast size / physical build. These differences are dependent on other factors such as genetics and not just hormone levels.

Some of these changes (notably breast development) are likely to be permanent and not completely resolve on stopping hormone treatment.

Table 3: Expected effects from feminising hormone treatment

Effect	Expected Onset	Expected Maximum Effect
Body fat redistribution	3-6 months	2-5 years
Decreased muscle mass/strength	3-6 months	1-2 years
Softening of the skin/decreased oiliness	3-6 months	unknown
Decreased libido	1-3 months	1-2 years
Decreased spontaneous erections	1-3 months	3-6 months
Erectile dysfunction	variable	variable
Breast growth	3-6 months	2-5 years
Decreased testicular volume	3-6 months	2-3 years
Decreased sperm production	Variable	variable
Thinning and slowed growth or facial and body hair	6-12 months	>3 years
Scalp hair loss	No regrowth, loss stops 1-3 months	1-2 years

Source: Adapted from Hembree et al (2009). Effects also dependant on genetics, exercise, build.

2.6. Fertility and contraception

Fertility

Prior to the initiation of feminising gender affirming hormone treatment the individual should be made aware that hormonal preparations impair fertility. Prior to starting

feminising treatment, future fertility options need to be explored. Should the person wish to preserve their fertility then referral to the local fertility clinic/fertility preservation team should be made, ideally prior to starting full dose hormone treatment. See Fertility Preservation for more details.

2.7. Contraception

Hormone treatment is not reliable contraception and if required contraception should be used.

2.8. Treatment options

Feminising gender affirming hormone treatment is achieved by giving oral or transdermal estradiol preparations often in combination with GnRH suppression of the reproductive axis. Estradiol is introduced gradually and slowly titrated to avoid adverse reactions and subsequently a GnRH analogue added if needed.

Most preparations used do not have specific marketing authorisation for use as a gender affirming treatment. See Appendix 2 for guidance in prescribing medication out-with their marketing authorisation. Advice regarding hormone treatment is in line with guidance for prescribing out with marketing authorisation sometimes referred to as “off licence”.

2.9. Starting doses and dose titration

The option for oral or transdermal oestradiol preparations should be discussed at the initial visit highlighting the more favourable risk profile associated with transdermal preparations. Transdermal preparations should be favoured for individuals over 40 and in patients with cardiovascular risk factors, high BMI, liver disease taking in account individual preference.

Gradual introduction of estradiol alone is recommended as detailed in the table below.

For higher risk individuals, it is recommended that a low dose of a transdermal preparation is started with more gradual dose titration than detailed in the table below. For example an initial starting dose of a 25mcg estradiol patch used twice a week with titration to a 50mcg patch after 2 months and no further initial dose titration until review. Individual circumstances and preferences should be taken into consideration when deciding on initial dosing regimens.

Review at 4 months with monitoring of estradiol and testosterone levels. Aim for estradiol concentrations of 200-600 pmol/l (based on mid follicular range). Usually levels in the middle of this range are acceptable for feminisation and general health. Timing of blood sampling should be considered when interpreting levels. Pharmacokinetic data are often not readily available for estradiol preparations and there is evidence that levels 24 hours after an oral preparation can fall to baseline and

blood sampling soon after gel application especially from the arm used for application can lead to spurious high levels. It is suggested that estradiol levels should be taken 48hours after a patch has been applied. When discussing levels and dose adjustments an individual's preferences and wellbeing should be considered.

At the 4 month review estradiol dose can be adjusted and a GnRH analogue added as needed if serum testosterone concentrations are outwith female range and depending on an individual's preference.

Table 4: Recommended starting doses/titration and usual maintenance doses for estradiol preparations

Preparation	Starting dose	titration	Usual maintenance dose
Oral estradiol	1 mg	Increase by 1mg/month to initial maximum dose of 4mg	2-6mg
Estradiol patch 25mcg patch changed twice weekly	25mcg patch changed twice weekly	After 1 month change to a 50mcg patch changed twice weekly, after a further 1-2 months change to a 75mcg patch changed twice weekly	50mcg – 200mcg patch changed twice weekly
Oestrogel	1 measure a day	Start with 1 measure a day and titrate up by 1 measure a month for the first 4 months	2 - 4 measures a day
Sandrena gel	1mg	Start with 1mg and titrate by 500mcg a month to initial maximum dose of 3mg	1 – 3mg daily
Lenzetto transdermal spray	1.5mg (1 spray)	Start with 1 spray and increase by 1 spray a month for the first 4 months	2-4 sprays daily

Oral and transdermal estradiol prescribing can be generic. Advice on dose alternatives can be found in Appendix 4.

2.10. Androgen suppression

Androgen suppression is recommended for individuals who do not suppress androgen levels with oestrogen alone. This occurs in approximately 1 in 3 patients after 3-6 months. Standard practice would be GnRH suppression of the reproductive axis using GnRH analogues. Examples include:

- Leuprorelin/triptorelin 3.75mg 4 weekly,11.25mg 12 weekly or 22.5mg triptorelin 6 monthly by IM injection OR
- Goserelin 3.6mg implant subcutaneously 4 weekly or 10.8 mg implant 12 weekly

Other agents

- Cyproterone acetate would not usually be used as a long-term treatment due to concerns relating to liver toxicity and increased risk of meningioma. There is evidence that 10mg daily is sufficient for suppression, but only 50mg tablets are available.
- Finasteride 5mg daily and spironolactone (50 -100mg daily) are not recommended as they are less effective in androgen suppression and associated with other side effects.

2.11. Typical maintenance estradiol regimes

- Maintenance dose is determined by estradiol levels. Target levels usually not higher than 600pmol/l (based on mid follicular range).
- Transdermal estradiol patches twice weekly (usual maximum dose 200mcg changed twice weekly) OR
- Oral estradiol (usual maximum dose 6mg daily) OR
- Estradiol gel approx. 4 measures a day
- If there are availability issues, it is acceptable to switch to other equivalent prescriptions. Generic prescribing is recommended.

Currently, progesterone (or synthetic progestogens) is of no proven benefit in this patient group and is not recommended due to potential associated risks. This approach would be consistent with female sex hormone treatment for any individual without a uterus.

2.12. Monitoring of hormone treatment

Monitoring of hormone treatment should be done on a 3-4 monthly basis whilst doses are titrated and within the first 2 years on gender affirming treatment. This will include:

- Serum estradiol (aiming for levels not higher than 600 pmol/l).
- Testosterone
- LFTs
- Routine monitoring of prolactin is not necessary unless there are relevant symptoms such as galactorrhoea, new headaches or visual disturbance.

2.13. Annual monitoring

When an individual is established on feminising gender affirming hormone treatment a minimum of 2-yearly review is recommended. This could include:

- Blood pressure, height, weight and lipid profile
- Cardiovascular risk assessment using ASSIGN or QRISK 3 at baseline and then at age 40yrs. Cardiovascular risk should be managed as per standard female guidance.
- Estrogen dose and route may need to be adjusted if there are concerns regarding risk of venous thrombo-embolism (VTE) or cardiovascular disease, or abnormal LFTs. Transdermal preparations are associated with lower risk and should be considered for people with higher cardiovascular risk (e.g. QRISK3 5-10%). Strong recommendation for transdermal preparations for women with a high cardiovascular risk (e.g QRISK3>10%) and all women over the age of 50.

Considerations later in life

- Feminising hormone treatment can be continued lifelong if desired and if the benefits outweigh the risks. The dose/route may be adjusted depending on risk factors
- For trans women who have undergone orchiectomy discontinuing feminising endocrine therapy later in life (over age 50 years) could be considered. The expected effects of this might be similar to the menopause.
- Withdrawal of feminising endocrine therapy in trans women who retain their gonads would result in a return of virilisation.

Reduction or withdrawal of feminising endocrine therapy later in life must involve discussion with the individual, taking into account their wishes, preferences, understanding and acceptance of risk.

2.14. Surgery

- Individual guidance regarding cessation and restarting of hormone treatment should always be sought from the surgical team.
- For gender related surgery, surgeons currently recommend that estrogen treatment should be ceased 6 weeks prior to surgery, and resumed 3 weeks after surgery if there are no complications.
- Androgen suppression is not required after orchidectomy.

2.15. Consent

If the person wishes to commence feminising gender affirming hormone treatment consent should be obtained using information in the consent form and this decision documented in medical records and shared with the GP.

2.16. Stopping hormone treatment

Any individual making the decision to stop hormone treatment should be adequately informed of the risks and benefits. Stopping treatment completely is rarely required purely on medical grounds. An individual may decide that the benefits do not outweigh the potential risk or they may feel that the desired effects have been

achieved. This is absolutely the person's choice and options should be discussed with an appropriately experienced professional.

Stopping treatment may lead to deterioration in mental health. Irrespective of the reason for stopping, individuals should be offered review and psychological support if required.

2.17. Hormone therapy for non-binary individuals

Some individuals seek limited effects from hormones or a mix of masculine and feminine characteristics. It is important to have a clear discussion regarding expectations and unknowns. It is not possible to select in advance an exact hormone regimen that will predictably allow an individual to arrive at a specified configuration of characteristics. Individual genetic and physiologic variation can result in wide variations in both blood levels and response to therapy between different individuals using the same route and dose. The best approach in these cases is to start with low doses and advance slowly, titrating to effect. The use of GnRH analogues without use of adequate sex hormone replacement would not be recommended.

3. Provision of Fertility Preservation in NHS Scotland

The purpose of this document is to set out the principles of provision and criteria for accessing NHS funded fertility preservation for TGD people. This document considers only fertility preservation through gamete/ovarian tissue cryopreservation for those who are pubertal or adult.

Fertility preservation is relevant to TGD individuals. Fertility preservation is a relatively new speciality with an emerging evidence base. The recommendations below are therefore based largely on national and international guidelines (e.g. WPATH and the European Society for Human Reproduction and Embryology [ESHRE]), and taking into account the current provision of assisted reproduction services in NHS Scotland.

The over-riding principles of access to NHS funded fertility preservation are that:

- A specific, imminent and significant risk to the patient's fertility is identified. Quantifying that risk is difficult and may be uncertain at the time of referral, but where it is clinically judged to be low (estimated on available evidence to be <30%), FP will not be offered.
- A pathway of medical intervention exists that has the potential to successfully address the risk to the patient's fertility
- There is a route to achieving a successful pregnancy and birth of a child for that patient in the future

- Any clinical risks to the patient from the required intervention (and where relevant, of subsequent pregnancy) are identified
- Long-term survival of the patient is expected, with the ability to be able to use their stored gametes.

It is important that all relevant patients are offered a consultation with an appropriately trained medical/paramedical member of staff, and that there is provision of information on the full range of methods for fertility preservation that might be appropriate for that individual. In general, this discussion will take place at the referring clinic (ie the gender identity clinic [GIC]) with referral to assisted reproduction only where the patient is keen to proceed to a fertility preservation procedure, and access criteria are met. It is recognised that the details of relevant procedures are likely to be outwith the knowledge of staff at the GIC, but such staff should have sufficient knowledge to be able to provide initial information, and signpost patients to further information.

3.1. Referral pathways and initial assessment considerations

Pathways for referral need to be developed locally that ensure timely receipt of referral from relevant clinical services. A template referral form should be used by the referring GIC (consultant or specialist nurse) giving an outline of the diagnosis and proposed treatment, other relevant medical issues, and documenting completion of any relevant initial tests.

In many cases the decision to proceed to fertility preservation can be made simply and quickly. However, for more complex cases, discussion by a review group with multi-disciplinary expertise from all four Scottish Fertility Centres has now been established and should be used to help with decisions to ensure that these are consistent between the centres. Record keeping will allow past decisions to be recalled. Documentation of the key issues raised by the case, the decision made and the outcome will be recorded to allow reference to previous decisions.

There are four NHS Fertility Centres in Scotland that provide fertility preservation for those patients that require this treatment. Travel costs for patients where required will be met.

3.2. Specific issues regarding TGD individuals

1. Referral pathways: only patients who have been assessed and referred by the GIC as suitable for gender reassignment will be considered. Initial discussion of fertility preservation will be provided by the GIC prior to referral, when early information provision about the effect of gender reassignment on fertility and fertility options will be provided. The HFEA has developed specific information related to this (https://www.hfea.gov.uk/treatments/fertility-preservation/information-for-trans-and-non-binary-people-seeking-fertility-treatment/).
2. An appointment with the fertility clinic counsellor should be arranged initially.
3. Discussion will include consideration how the gametes will be used in the future as well as just storage, although it is recognised that there may be considerable

uncertainty about potential use when patients are just about to start on hormones or other treatment and options must be kept open. Options may include surrogacy or stopping gender affirming hormone treatment.

4. The effect of trans-endocrine treatment on fertility is considered reversible, however it is likely that many people would not want to stop treatment once initiated for the several months that would be required. Guidance on the appropriate pathway for people already taking gender-affirming hormone treatment is given in the next section.
5. Clinics need to be sensitive to dysphoria and should provide gender-neutral signage whenever possible. Transvaginal egg recovery is a central part of the process of egg storage. Transabdominal egg recovery is only appropriate where the ovaries are physically not accessible transvaginally.
6. Some people may later choose or require surrogacy. This may not be known at the time of gamete storage and has issues for whether subsequent use will count as 'gamete donation' and thus what clinical activities/tests are required. Please see Appendix 2 for details of how to approach this.

3.3. TGD patients already taking gender-affirming hormone treatment

While it is preferable for TGD people to store eggs or sperm before starting gender-affirming hormone treatment, sometimes this is not possible, and consideration must be given to how best to manage that situation. In some cases, it may be considered more appropriate to defer gamete storage (perhaps for years) despite imminently starting gender affirming hormone treatment, to allow continuing consideration of the wish for such storage. Gamete storage can be considered at any time up until surgical removal of the gonads.

3.4. For egg cryopreservation

The procedures required prior to oocyte cryopreservation, such as hormonal ovarian stimulation and transvaginal ultrasound (TVS), have a negative impact on gender dysphoria; successful management requires sensitivity and awareness of these issues, eg offering transabdominal ultrasound monitoring (Armound et al 2017).

Patients may be on testosterone, and some also on GnRH agonists. Thus they will be hypogonadotrophic - much like people on long-term agonists eg for endometriosis. Importantly, intrafollicular testosterone concentrations are 100-200 nmol/l (Kristensen et al 2018), thus serum testosterone concentrations are not relevant to the huge concentrations that the oocyte is exposed to during normal development. Successful ovarian stimulation and oocyte storage have been reported without prior cessation of testosterone treatment, though only in a single individual at present (Cho et al., 2020), and most of the literature is on trans men who have stopped testosterone treatment for some months prior to ovarian stimulation.

Options for ovarian stimulation:

1. Lower testosterone dosage while maintaining some gender-affirming effect can be achieved by using testosterone gel at eg 25mg/day for 2-3 months before ovarian stimulation. This is likely to allow at least partial recovery of

gonadotrophin section and ovarian activity, which may have a positive effect on the response to ovarian stimulation.
2. If the person is established on GnRHa, continue as per long-cycle conventional stimulation
3. Letrozole may be added during ovarian stimulation to minimise the rise in estradiol levels.

There seems no justification to require patients to stop gender affirming hormone treatment before starting ovarian stimulation. This is the practice in other centres with substantial experience of this.

3.5. For sperm cryopreservation

Patients may be on long-term GnRH agonists and estradiol treatment. They will be markedly hypogonadotrophic, and spermatogenesis will be suppressed (though not always completely). There is also some evidence that even before endocrine treatment is started, trans women are more likely to show oligospermia (Li et al 2018), possibly due to tucking: this practice should be specifically enquired about, as its effect on spermatogenesis is fully reversible.

Patients started on GnRH agonists at the time of puberty may never have initiated or fully established spermatogenesis: it is likely that a very prolonged period of stopping treatment will be necessary for establishment of spermatogenesis.

The procedures for sperm cryopreservation may have a negative impact on gender dysphoria; successful management requires sensitivity and awareness of these issues.

Options

4. Assess sperm production at presentation. If there are sperm present, store them. More than one semen sample may be needed to ensure an adequate number of sperm are stored.
5. If there is severe oligo/azoospermia, discuss stopping endocrine treatment. It may take many months for spermatogenesis to be restored, and stopping treatment may not be acceptable to some patients.
6. If they do accept to stop treatment, it seems reasonable to offer a repeat assessment at 3-6 months and at intervals thereafter, until sufficient sperm can be stored.

3.6. Access criteria

The principle for these is that they should largely be in line with nationally agreed access criteria for assisted reproduction, while recognising the special circumstances surrounding fertility preservation. All NHS patients will be assessed using the same equitable criteria for treatment and storage.

1. For those storing eggs/embryos, BMI needs to be under 35. This differs from IVF criteria (due to time constraints).

2. Upper cut off age for oocyte/embryo/ovarian tissue fertility preservation should be 41.
3. There is a need for an upper age limit for those storing sperm, although this is based on less clear grounds. The group considered that 53 years is an appropriate age limit for those storing sperm because of increasing risk to offspring with paternal age.
4. The individual proposing to store gametes will have no biological children, or not be a legal parent.
5. Previous sterilisation will preclude access.
6. Smoking would not preclude access to storage; however where there is time, patients should be strongly encouraged to stop smoking.
7. Being in a stable relationship is not a relevant criterion for access (or ongoing storage)
8. If they are in a relationship, whether the partner meets IVF access criteria (eg BMI) is not relevant.

It is essential that patients recognise that full IVF access criteria will apply when it comes to using stored material for assisted conception in an NHS setting.

3.7. Treatment to be offered

Egg/embryo storage: one cycle of ovarian stimulation will be offered. When it is considered that the ovarian stimulation regimen did not result in an optimal response for that patient, a second stimulation may be considered. The number of eggs stored is not the basis for whether a second cycle is offered.

Sperm storage: this may involve the storage of sperm obtained from more than one ejaculate or a surgical sperm extraction procedure. Centres may offer storage of up to 3 ejaculates, but this may be limited by the time available and may not be necessary if the sample quality is high.

3.8. Information provision

Patients should be provided with verbal and written information at all stages, ie both in the referring clinic and in the assisted reproduction clinic. The use of Near Me in conjunction with the “Language Line” telephone interpretation service and “face to face” language or British Sign Language (BSL) interpreters may be appropriate for non-English speaking people.

Patient information leaflets in line with this guidance are available (Appendix), for sperm and egg storage. Information is available from the HFEA website (including information specific for TGD people):
https://www.hfea.gov.uk/treatments/fertility-preservation/

3.9. Counselling

Access to a specialist fertility Counsellor will be offered to patients prior to their giving consent to treatment (on, among other things, the implications of taking the proposed steps) and following fertility preservation.

The HFEA Code of Practice states that fertility centres should provide a suitable opportunity for counselling after the individual or couple has received oral and written information about the services to be provided and before they consent to treatment, donation, or to the storage or use of gametes or embryos. The HFEA also state that the centre should provide proper counselling throughout the treatment, donation or storage processes, and afterwards if requested.

3.10. Ongoing NHS storage of gametes

Current HFEA regulations use duration of storage rather than age. The main upper age limit for NHS IVF treatment in Scotland is a female age of 40 however Scotland follows the NICE guidance which allows for women aged 40 to 42 to have one cycle of NHS IVF treatment if they meet certain criteria, therefore gametes in storage after that age cannot be used for NHS treatment.

1. The above access criteria specify the cut off age for starting storage of gametes should be 41 for egg/embryo storage and 53 for sperm storage, at time of storage (ie fertility preservation treatment to be initiated before 42nd/ 54th birthday).
2. Patients should have a 5 year follow up initiated by the fertility clinic that provided storage (with further assessment as required) to assess whether it is appropriate to continue NHS funded storage.,
3. Not being in a stable relationship is not a relevant criterion for either initiating storage, or for ongoing storage.
4. Young patients may need to store gametes for a very long time.
5. If at follow up review the patient is not eligible (e.g. now has children, or age >42 for oocyte storage or 55 for sperm storage, i.e up to 43rd/56th birthday) then ongoing NHS funded storage will not be provided. A review appointment offers the opportunity for discussion/assessment (potentially also with an appointment with the fertility clinic counsellor) without denying ongoing storage, which may need to be at the patient's own expense.
6. It is considered that a normal semen analysis indicates likely fertility, and certainly shows the presence of sperm which could potentially be used in assisted conception. If at the 5 year appointment or thereafter the patient is shown to have a normal semen analysis, there should be a discussion regarding disposal of stored sperm; or alternatively, ongoing storage will need to be at the patient's expense. If however the sperm count is found to be low then ongoing storage will be provided. If the patient does not provide a semen

sample, further storage at NHS expense will not be provided, and the stored samples will be disposed of or with further storage at the patient's expense.

7. Regular menstrual cycles or biochemical tests of ovarian function should not be used as grounds for disposal or charging for ongoing storage of oocytes, where other criteria for access to NHS treatment are still met.
8. A patient contract is considered the best way of combining these aspects of duration of storage, the need to reassess eligibility, and self-funding of further storage. This needs to be completed at the time of storage.

3.11. Data Collection

It is important that information regarding use of NHS resources is collected, and this will become a valuable and robust data set informing future service development. Information to be collected includes:

1. Number and source of referrals
2. Number of patients proceeding to fertility preservation; their characteristics (e.g. age, diagnosis) and FP results (e.g. no of eggs)
3. Ultimately, data on usage/other outcomes.

ISD have developed a data capture form which has been circulated to all centres to start using immediately, with the opportunity for revision to improve functionality. Centres will send completed forms to ISD monthly to align with their IVF returns. ISD will collate data at quarterly intervals. Centralised storage by SNBTS will allow collection of these data with sample storage: this is being developed.

3.12. Funding options considered

The Fertility Scotland Strategic Plan has been approved by NHS National Services Division. Fertility Preservation is included in this plan.

Appendix 1: Medical conditions and testosterone

Cardiovascular disease and cardiovascular risk

Testosterone treatment has been shown to increase cardiovascular risk in some studies. Testosterone treatment can also be associated with an increased haematocrit which will increase cardiovascular risk and may worsen cardiovascular disease. In most population studies men have increased cardiovascular risk compared to women. Reasons for this are not fully understood but will partly relate to genetics and hormones.

People starting testosterone treatment should have a discussion about cardiovascular disease and have their cardiovascular risk calculated using a risk calculator such as QRISK3 or assign. Generally risk should be assessed using male gender.

There are no large studies assessing testosterone treatment in people specifically taking testosterone as a gender affirming treatment. Advice is extrapolated from population studies and testosterone treatment studies. Established cardiovascular disease and cardiovascular risk factors should be treated as per general population.

Polycythaemia/raised haematocrit

- Testosterone will increase FBC production and therefore haematocrit. Increased haematocrit is associated with increased cardiovascular risk.
- Haematocrit should be monitored for people on testosterone.
- When assessing FBC and Haematocrit, local male ranges should be used. A haematocrit should be measured 4-6 months after every dose titration and then yearly for people on a stable dose
- Risk of polycythaemia can be reduced by addressing other risk factors such as smoking and obesity.
- Aim for haematocrit of ≤ 0.5
- If HCT >0.5 first step is to reduce dose of testosterone either by increasing interval between injections or reducing dose of gel.
- For some people it may not be possible to achieve acceptable testosterone levels while maintaining a HCT <0.5. In this situation can accept a HCT of >0.5 but in normal range (most labs <0.52) providing the person has been counselled about risk of increased haematocrit.
- Other cardiovascular risk factors should be treated
- Seek guidance if haematocrit is significant elevated as urgent venesection may be required.

Hypertension

- BP should be monitored and treated as per general population using standard risk calculators to determine targets.

Diabetes

- Men have an increased risk of diabetes. Screening and treatment should be as general population

Liver disease

- Oral testosterone has been associated with impaired liver function and liver tumours. Oral testosterone is not recommended. There is no evidence that transdermal or IM preparations affect liver function/ cause liver tumours. Impaired liver function/liver disease should be investigated and managed as per general population. There may be a need to adjust the dose of testosterone.

Breast disease

- Testosterone has been associated with male breast cancer. There is no evidence of increased risk of breast cancer in this group. For people with breast tissue breast screening should be performed as per guidelines. Breast screening is not required after mastectomy or chest reconstruction. Breast lumps should be investigated as per general population

Abnormal PV or menstrual bleeding, and prolonged amenorrhoea

Testosterone treatment will usually cause cessation of periods. Studies have looked at endometrium in people on testosterone with both atrophic and hypertrophic endometrium being found on biopsy. There is currently insufficient evidence to suggest routine ultrasound scanning to assess endometrial thickness for people on testosterone, however people with new bleeding developing on full dose testosterone, or who have abnormal bleeding should be investigated as per standard guidelines.

Benign Intracranial Hypertension

Testosterone has been associated with Benign Intracranial Hypertension. Obesity and polycystic ovary syndrome also appear to be risk factors. Testosterone may be stopped at least until intracranial pressure, papilloedema and visual disturbance improve. Testosterone treatment may be restarted with the agreement of neurology and endocrinology specialists. The preparation or dose may need to be adjusted to minimise the risk of recurrence. Testosterone may need to be stopped or reduced, and this should be discussed with individual.

Appendix 2: Marketing authorisation and “off label” use

A marketing authorisation (MA), previously called a product licence, is granted by a regulatory body to a pharmaceutical company for a specific medicinal product. It specifies the terms of use, including the indications, doses, routes and patient populations for which it can be marketed

Although there is no official definition, generally ‘off-label’ describes the use of a medicinal product beyond the specifications of its MA, e.g. for an indication or in a dose, route or patient population not covered by the MA.

Most of the testosterone preparations described in this guidance do not currently have marketing authorisation for masculinising gender affirming hormone treatment. The GMC has specific guidance for prescribing unauthorised medicinal product, with key points below.

The General Medical Council (GMC) recommends that when prescribing off-label or prescribing an unauthorised medicinal product, doctors should:

- be satisfied that such use would better serve the patient’s needs than an authorised alternative (if one exists)
- be satisfied that there is sufficient evidence/experience of using the medicinal product to show its safety and efficacy, seeking the necessary information from appropriate sources
- record in the patient's clinical notes the medicinal product prescribed and, when not following common practice, the reasons for the choice
- take responsibility for prescribing the medicinal product and for overseeing the patient’s care, including monitoring the clinical effects, or arrange for another suitable doctor to do so.

The guidance given regarding testosterone treatment is in line with this GMC guidance.

Appendix 3: Medical conditions and estrogen

Venous thromboembolism

Venous thromboembolism is the most important potential complication of oestrogen treatment. A 20-fold increase in venous thromboembolic disease was reported in a large cohort study. However this increase may have been associated with the use of ethinyl estradiol which is now not standard practice. The same results are not replicated in large cohort studies with trans women on relatively high doses of estradiol (E2) where only single cases of VTE were observed.

Osteoporosis

Estrogen preserves bone mineral density in people who continue on estrogen and antiandrogen therapies.

Breast cancer

A few cases of breast cancer in trans women have been reported in the literature. In a large Dutch cohort of 1800 trans women followed for a mean of 15 yr only one case of breast cancer was found. The Women's Health Initiative study reported that women taking conjugated equine estrogen without progesterone for 7 yr did not have an increased risk of breast cancer as compared with women taking placebo. Women with primary hypogonadism (XO) treated with estrogen replacement exhibited a significantly decreased incidence of breast cancer as compared with national standardized incidence ratios. These studies suggest that estrogen treatment does not increase the risk of breast cancer in the short-term. Long-term studies are required to determine the actual risk. Monthly breast checks and breast screening as per people assigned female is recommended.

Prostate cancer

Prostate cancer is very rare, especially with androgen deprivation treatment but an awareness of prostate disease should be retained by trans women and clinicians.

Prolactinoma

Estrogen treatment can increase the growth of pituitary lactrotroph cells and result in hyperprolactinaemia. Given that prolactinomas have been reported only in a few case reports the risk of prolactinoma is likely to be very low. Prolactin should be checked at baseline and during titration of oestradiol doses and in individuals presenting with headache, visual disturbance or galactorrhoea. Prolactin persistently >1000mU/l should be investigated as per standard guidance including pituitary MRI.

Cardiovascular disease

A prospective study of trans women found favourable changes in lipid parameters. However. There was also increased weight, blood pressure, and markers of insulin resistance. The largest cohort of trans women (with a mean age of 41 yr) followed for a mean of 10 yr showed no increase in cardiovascular mortality despite a 32% rate

of tobacco use. Thus, there is limited evidence to determine whether estrogen is protective or detrimental in trans women.

Appendix 4: Preparations and dose alternatives

The following tables are helpful for writing prescriptions and switching hormone treatment. Information on starting, titrating and maintenance doses is available in the main sections of this document.

Preparation	Alternative to 2mg oral estadiol daily
Oral estradiol (e.g Elleste Solo 2mg, Zumenon 2mg or Progynova 2mg)	2mg daily
Estradiol patches (e.g. Estraderm MX, Estradot, Evorel)	50 microgram/24hour patch used twice weekly
Oestrogel	1 pump twice a day
Sandrena gel	1mg sachet daily
Lenzetto transdermal spray	3 sprays daily

Testosterone Gel Preparations and Doses per Pack

Brand name	Container	Concent-ration	Metered dose	Pack size	Metered doses per pack
Tostran ®	canister	20mg/g	10mg in 0.5g	60g	120
Testogel ®	pump	16.2mg/g	20.25mg in 1.25g	88g	60
Testogel ®	sachet	16.2mg/g	40.5mg in 2.5g sachet	30 x 2.5g	N/A
Testavan ®	pump	20mg/g	23mg in 1.15g (1.25ml)	85.5g	56
Testim®	tube	10mg/g	5g tube	30 x 5g	N/A

Estradiol Preparations used for Feminising Gender Affirming Treatment and Approximate Equivalent Doses*

Estradiol Preparation	Commonly Prescribed Strengths**	Number of doses per pack	Level of Dose		
			Starting/ Low Dose	Medium Dose	Higher Dose
Oral tablet	1mg 2mg	84 tablets	1mg daily	2mg daily	3-4mg daily

Patch	25 mcg 50mcg 75mcg 100mcg	8 patches	25mcg twice weekly	50-75mcg twice weekly	100-150mcg twice weekly
Gel Pump (Oestrogel® 0.06%)	0.75mg per 1.25g press	64 doses per 80g pump	1 press daily	2 presses daily	3-4 presses daily
Gel sachet (Sandrena®)	0.5mg 1mg	28 sachets	1mg daily	1.5mg daily	2-3mg daily
Spray (Lenzetto®)	1.53mg per spray	56 sprays per pack	1 spray daily	3 sprays daily	4 sprays daily

* This information is provided as a practical guide based on a combination of pharmacokinetics, clinical trials and clinical experience. Levels of dose are approximate as there is wide inter- and intra-individual variation between the clinical response to different preparations and estradiol serum levels. Higher doses may be required for some individuals.

**Other strengths of patch and of conjugated oral oestrogen are available.

Appendix 5: Gamete storage for use by 3rd party reproduction

Some patients undergoing gamete storage may subsequently require 3rd party reproduction (donation and surrogacy). For this, they are considered to be gamete donors, requiring additional screening tests, as specified in the current HFEA Code of practice that the donor is tested for cystic fibrosis, karyotype, cytomegalovirus, syphilis and gonorrhoea and blood group (in addition to standard viral testing) and completes a questionnaire regarding risk of genetic disease.

The need for surrogacy will often be unclear at the time of gamete storage. Options would therefore be to (i) treat all as potential donors, (ii) treat selected individuals as potential donors, or (iii) treat none as potential donors and undertake additional screening at the time of use.

Considerations include:

- Unnecessary investigations at storage, with cost and inconvenience considerations.
- Infection tests changing between storage and use: these tests therefore need to be undertaken at storage for optimum validity.
- Tests that will not change are CF, karyotype, blood group: these could therefore be undertaken at time of use.
- Questionnaire: important for identification of recent travel/infection risk.

All individuals undergoing gamete storage should be assessed as to the potential need for 3rd party reproduction, recognising that the individual's situation in the years to come is difficult to predict. This applies equally to those storing sperm and eggs, and it is important to recognise that this possibility should be discussed (and recorded) with all patients proceeding to fertility preservation procedures. If there is considered to be a possibility of needing 3rd party reproduction, the following approach should be taken:

- Infection-related tests should be done at the time of gamete storage, with medical/behavioural/social questionnaire
- Karyotype, blood group and CF screening should be done at time of gamete use, not at the time of gamete storage.
- Genetic questionnaire: to be completed at the time of gamete use.

Not doing these tests at time of storage will not preclude later use in donation, except where infection tests are positive at time of potential donation and would have been negative at time of storage (but were not done).

Appendix 6

Development Group membership

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Acknowledgements

The individual needs of people accessing gender identity healthcare was at the heart of this work. We engaged widely with people using or interested in accessing services and also with professional organisations.

Individuals with lived experience were asked if they would like to provide subsequent information to the by participating in 1-2-1 interviews. These individuals' added suggestions and revisions, in addition to those supplied through the web form surveys.

NHS National Services Division would like to thank everyone who was involved in the working groups and who responded to our requests for feedback.

If you have any further queries, please contact the team at nss.grp@nhs.scot

Reference list

Armuand G, Dhejne C, Olofsson JI, Rodriguez-Wallberg KA Transgender men's experiences of fertility preservation: a qualitative study.Hum Reprod. 2017;32:383-390

Cho K, Harjee R, Roberts J, Dunne C. Fertility preservation in a transgender man without prolonged discontinuation of testosterone: a case report and literature review. *F S Rep* 2020;1: 43-47.

Kristensen SG, Mamsen LS, Jeppesen JV, Bøtkjær JA, Pors SE, Borgbo T, Ernst E, Macklon KT, Andersen CY. Hallmarks of Human Small Antral Follicle Development: Implications for Regulation of Ovarian Steroidogenesis and Selection of the Dominant Follicle. Front Endocrinol (Lausanne). 2018 12:376.

Li K, Rodriguez D, Gabrielsen JS, Centola GM, Tanrikut C Sperm cryopreservation of transgender individuals: trends and findings in the past decade. Andrology. 2018;6:860-864.

ESHRE Guideline Group on Female Fertility Preservation, Anderson RA, Amant F, Braat D, D'Angelo A, Chuva de Sousa Lopes SM, Demeestere I, Dwek S, Frith L, Lambertini M *et al.* ESHRE guideline: female fertility preservation. *Hum Reprod Open* 2020;2020: hoaa052.

NICE Clinical Guideline 156 Fertility: assessment and treatment of people with fertility problems (2013) http://guidance.nice.org.uk/CG156

HFEA website information regarding fertility preservation for all patients: https://www.hfea.gov.uk/treatments/fertility-preservation/

HFEA information specific to transgender individuals https://www.hfea.gov.uk/treatments/fertility-preservation/information-for-trans-and-non-binary-people-seeking-fertility-treatment/

Van Kesteren PJ, Asscheman, H, Megens, JA, Gooren, LJ (1997 Mortality and morbidity in transsexual subjects treated with cross-sex hormones.*Clin Endocrinol (Oxf)* 47 337342

Arnold JD, Sarkodie EP, Coleman ME, Goldstein DA. Incidence of venous thromboembolism in transgender women receiving oral estradiol. J Sex Med. (2016) 13:1773–7. doi: 10.1016/j.jsxm.2016.09.001

Ott J, Kaufmann U, Bentz EK, Huber JC, Tempfer CB. Incidence of thrombophilia and venous thrombosis in transsexuals under cross-sex hormone therapy. Fertil Steril. (2010) 93:1267–72. doi: 10.1016/j.fertnstert.2008.12.017

SHARED CARE AGREEMENT

Name of medicine	*Feminising Endocrine Treatment (Estradiol and GnRHa)*
Indication	*Gender dysphoria/incongruence after assessment at the GIC for over 18 year olds*

Version: 1.0 Approval date: **September 2024** Review date: **September 2027**

The Shared Care Agreement (SCA) is intended to facilitate the accessibility and safe prescribing of complex treatments across the secondary/primary care interface. It does not contain all of the relevant product information, which should be sought using the current British National Formulary and manufacturer's Summary of Product Characteristics. The SCA must be used in conjunction with the NHS Lothian Procedure for the Shared Care of Medicines, available here.

Roles and responsibilities

Chalmers Gender Identity Clinic (GIC) will undertake initial assessment to establish treatment and then recommend prescribing for all those seeking feminising endocrine treatment. GPs will be asked to be undertake the prescribing and reporting of any issues to the GIC from the commencement of treatment.

However, recall and monitoring (including phlebotomy and blood pressure measurement) will be undertaken by the GIC, who will also arrange any clinical review required. The GP will then be asked to prescribe accordingly. This has now been agreed with the Lothian GP Sub-Committee.

This document uses the term **trans women** to include trans women and non-binary people (recorded male at birth) using feminising hormones in connection with gender dysphoria or incongruence.

Listed below are specific responsibilities that are additional to those included in the NHS Lothian Policy and Procedures for Shared Care. Please refer to the policy for core roles and responsibilities that apply to all Shared Care Agreements.

Consultant

INITIAL SPECIALIST ASSESSMENT - GIC:

- Baseline assessment, treatment counselling, gaining informed consent and recommending initiation of treatment (communicated to GP to prescribe). This will include consent for the unlicensed use of medications
- Provide information both to the GP and the patient outlining risks of treatment
- Monitoring for the first year (or until patient is on a stable medication regimen)
- Communication with the GP about any changes in treatment
- Referral for specialist interventions relating to gender reassignment and transitioning
- Referral for non-specialist interventions suggested by the GIC (e.g. CMHT, weight management etc)
- Advise about changes in CHI, breast cancer screening, prostate awareness and over-65 Abdominal Aortic Aneurysm screening – details available from national screening programmes
- Assess cardiovascular risk status (ASSIGN score) and advise appropriately. The literature suggests that the cardiovascular risks are those of untreated non transgender men, so the GIC recommendation is to use male gender in the risk calculation
- Assess thrombo-embolic risk and advise appropriately
- There should be no need for additional bone protection, except in the rare situation of someone having had gonadal removal who is not also taking hormonal therapy. Please note the advice about Vitamin D in Scotland and on standard osteoporosis management.

ONGOING CARE (shared):

The patient will be offered a review, every 1-2 years depending on level of clinical risk. This may be virtual with the option of Patient-Initiated Follow up (PIFU) with GIC if there are interim clinical issues, thereby retaining specialist clinical oversight.

The following will be organised by the GIC, with a recall system, to monitor ongoing hormonal therapy treatments:

- Maintain awareness of prostatic disease and institute appropriate investigations if lower urinary tract symptoms occur
- Undertake any BP measurements or blood tests required, review clinically as indicated by the patient's situation and risk and write to the GP to advise appropriate prescribing following this
- Check at review that the patient has not developed key conditions that would change hormonal prescribing - see monitoring summary.

General Practitioners and primary care non-medical prescribers

- Be aware of the potential for prostatic disease and institute appropriate investigations if lower urinary tract symptoms occur. Note that PSA monitoring is not required
- Institute changes in treatment as per GIC advice following review. If the patient does not attend necessary reviews, the GP will be informed and prescribing reviewed
- Inform the GIC
    - for risk re-evaluation for new diagnoses of cerebrovascular disease, coronary heart disease or venous thrombo-embolism
    - if new diagnosis of active liver disease or liver tumours

There will be a very small number of high-risk patients whose care – including prescribing - should be solely undertaken by the specialist service.

THERE IS A SUMMARY OF MONITORING REQUIREMENTS AT THE END OF THIS DOCUMENT.

Please note that for patients aged under 40 (the vast majority), unless there is a significant new diagnosis, the only monitoring requirement is for periodic BP and smoking advice. The only exception is the (very rare) patient on spironolactone or cyproterone.

Patient, relatives, carers

To attend for monitoring as requested.

To keep the GIC updated of any change to their name, address or phone number.

Support and Advice for the GP and primary care non-medical prescribers

Support and Advice for the GP

The GIC can be contacted by health professionals only for advice via SCI Gateway for Chalmers Sexual Health Centre, Gender Identity, otherwise clinical advice is available by email at loth.gic@nhs.scot Referrals are viewed weekly and we will answer any queries within 7 working days.

For more urgent advice you can phone the service admin team on 0131 5361570

Hormone therapies are recommended under the Endocrine and Fertility Preservation Guidance 2022, based on the Scottish Government Gender Reassignment Protocol 2012. This advice is regularly updated by the clinical network (NCGICNS) and the latest available at Endocrine Guidance – National Gender Identity Clinical Network for Scotland

Hormonal therapy may be recommended after the initial assessment is completed and the Lothian approach to prescribing and monitoring is supported by a multidisciplinary expert team.

New Patients

Some people will have been assessed by, or had treatment from, a recognised NHS gender identity clinic and are new to Borders, Fife or Lothian (the areas served by the GIC). If they have been assessed by an NHS GIC (or specialist gender service whilst resident overseas) the GIC can provide email advice on ongoing treatment or see patients where that is necessary. The GIC is unable to prioritise patients who have accessed private treatment and recommends that they are advised to continue their engagement with their existing provider until the GIC has completed its assessment.

For those moving into Scotland, please advise about the procedures for changing CHI numbers and enrolling in the relevant national screening programmes. CHI numbers are gender specific, the penultimate number of the CHI signifying female (even number) or male (odd number).

Key Information on the Medicine

Refer to current edition of the British National Formulary (BNF), available at www.bnf.org, and Summary of Product Characteristics (SPC), available at www.medicines.org.uk for detailed product and prescribing information and specific guidance.

Background and use of feminising endocrine treatment for gender dysphoria.

Hormone therapies are recommended under the Endocrine and Fertility Preservation Guidance 2022, based on the Scottish Government Gender Reassignment Protocol 2012. This advice is regularly updated by the clinical network (NCGICNS) and the latest available at Endocrinology Guidance (scot.nhs.uk). Hormonal therapy may be recommended after the initial assessment is completed and the Lothian approach to prescribing and monitoring is supported by a multidisciplinary expert team.

Oestrogen evidence base in non transgender women

The risks of exogenous oestrogen have been investigated in large studies of HRT in non transgender women, although this remains a debated area. The impact of age is however very important: for younger patients, the equivalent patient group would be women with premature ovarian insufficiency, but the evidence regarding risk in this group is very limited[i].

The oestrogen doses used for feminising treatment for gender dysphoria are generally higher than those used for HRT, but some of the evidence relating to HRT is likely to have relevance. It is important to note that some HRT risks largely relate to, or are magnified by, combined preparations (ie progestogen-containing) which are not used in trans women. These progestogen-related risks include VTE and breast cancer. Current understanding is that starting oestrogen-only HRT in a healthy 50-year-old woman increases life expectancy, largely related to **reduced** risk of cardiovascular disease.

It is however clear that exogenous oestrogen:

- *increases the incidence of venous thrombo-embolism (VTE), particularly with oral preparations, and this risk is dose-dependent*
- *also increases the risk of ischaemic stroke, particularly in older women. The CHD risk is reduced with oestrogen-only HRT in healthy peri/postmenopausal women but rises if combined HRT is started >10 years after the natural menopause*
- *increases the risk of breast cancer.*

For further information on the risks in non transgender women please see the relevant MHRA advice.

Oestrogen evidence base in trans women

The evidence base in trans women is very limited. A retrospective case-controlled study has shown that trans women on hormone therapy had a higher incidence of both VTE and ischaemic stroke[ii]. The risk differences for VTE at 2 and 8 years were 3.4 and 13.7 relative to non-transgender women on no oestrogen. In contrast to non-transgender women where the VTE risk rises soon after starting treatment, *the risks in the trans women study continued to rise over time*.

There may be an increased risk of MI, and the evidence suggests this, though the estimated risks are the same as those for non-transgender men. Whilst this is a relatively large study in this patient population, very few events were detected, and it was not possible to explore the effects of age or oestrogen dose. Thus, the precision of these risks, and their relevance to younger trans women, particularly with physiological levels of estradiol replacement, remain very unclear.

Older studies are generally poor, because of compounding factors, and that a variety of doses and preparations have been used historically.

Taking the available evidence together:

- *it is very clear that transdermal, rather than oral preparations have the lowest risk of VTE, and that the risk particularly with oral preparations is dose-dependent*
- *That VTE risk is likely raised, and it is also likely that it continues to rise with duration of use*
- *There may be an increased risk of MI (likely similar to non transgender men).*

Indication

Specific to approved use in NHS Lothian (check formulary status)

Dosage and administration

- Transdermal preparations, which avoid first pass metabolism in the liver, are strongly recommended for all patients especially those aged > 40 years and those with higher cardiovascular risk, a high BMI or liver disease. They are associated with reduced VTE risk compared with oral preparations
- Transdermal estradiol patches up to 200 micrograms, changed once or twice weekly according to manufacturer instructions (initial dose titration at CGIC)
- Estradiol gel 0.5mg to 3mg, applied daily
- Oral estradiol 1mg to 6mg daily.

Androgen Suppression

- Leuprorelin/Triptorelin 3/3.75mg 4 weekly or 11.25mg 3 monthly or 22.5mg (triptorelin) 6 monthly by IM injection **OR** Goserelin 3.6mg implant subcutaneously 4 weekly or 10.8 mg implant 3 monthly.

OR

- Cyproterone acetate (25-100 mg daily: 6 monthly checks of LFTs are necessary as serious hepatotoxicity has been reported). This is likely to be used only when patients are already taking it eg prior to moving to Lothian and is rarely prescribed.

Patients may require re-titration of estradiol following gonadectomy, when androgen suppression therapy can be stopped. All should re-engage with the GIC during this period, and the GIC will carry out this titration if indicated.

Estradiol levels up to 600 pmol/L are appropriate though regular screening of estradiol levels is not recommended. The GIC will base its advice regarding changing dose primarily according to clinical response.

Monitoring

There is some internationally recognised guidance for monitoring, but it too has limitations and this guidance reflects a Lothian pragmatic multi-disciplinary consensus view. Many of the recommendations for monitoring come from American practice, often over-interventional in relation to the available evidence. There is limited data on the long-term health risks of hormone treatment and patients should be made aware that this is the case and the importance of long-term monitoring. However, overall, the evidence strongly supports the use of interventions in gender dysphoria for better clinical outcomes in consideration of the emotional and psychological risk versus benefit to the patient. Additionally, for patients who have had surgical orchidectomy, exogenous treatment is their only source of sex steroids, which also bring benefits, for bone health for example.

Risks may change over the course of a lifetime and need to be reassessed where new morbidities become apparent. Trans women need to understand that they are at increased risk of the following complications.

1. **Breast cancer**

   Trans women taking oestrogen may be at risk of developing breast cancer because of the development of breast tissue. They should be made aware of this, and encouraged to participate in the national breast screening programme and be breast aware.

2. **Venous thrombo-embolism**

   Trans women taking oestrogen, and their clinicians, should remain vigilant about the increased risk of VTE, a complication which can happen several years after starting hormone treatment: risks may rise over time. The risk is minimised by taking transdermal oestrogen preparations, and the lowest effective dose.

   If someone suffers a venous thromboembolism, oestrogen therapy should be stopped until further assessments are made.

   All will be risk-assessed by the GIC at the commencement of treatment, and reviewed periodically by the clinic, but advice should be sought from the GIC, or other relevant specialties, should high-risk situations develop such as:

   - Known hereditary or acquired predisposition for venous thromboembolism, such as APC-resistance, (including Factor V Leiden), antithrombin-III-deficiency, protein C deficiency, protein S deficiency
   - The presence of multiple risk factors including family history or conditions with a strong association with VTE

Those undergoing major surgery with prolonged immobilisation may need additional prophylaxis.

3. Cardiovascular disease

3.1. The GIC will undertake ongoing cardiovascular risk assessments as outlined below, but all clinicians are encouraged to opportunistically support risk minimisation lifestyle advice:

- **Risk Assessment.** All will have an initial cardiovascular risk assessment (ASSIGN score, using male gender for the risk calculation) at commencement of therapy and be advised accordingly
- **Risk Minimisation.** All should be encouraged to minimise risk through a healthy lifestyle. The standard advice is for: smoking cessation, maintaining a healthy weight, drinking alcohol according to national guidance (maximum 14 units per week), exercising regularly and eating well. Further advice is available at: https://www.nhs.uk/live-well/
- **BP and smoking advice – periodic check (annually or biannually):**
- ASSIGN score 5 yearly (age 40-55) and 3 yearly after that to optimise adverse lipid and blood pressure management, using male gender in the risk calculation.

We suggest that:

- Hypertension be treated at the threshold for diabetes or target organ damage. This means active management for those with Stage 1 hypertension and blood pressure readings of: clinic BP≥140/90 (multiple readings) and confirmed by subsequent ABPM daytime average ≥135/85 in keeping with the Lothian Hypertension Guidelines
  - Raised blood pressure: GIC will ask GP to review, undertake further investigation and initiate treatment where required
  - Abnormal lipids and/or elevated ASSIGN score: GIC will ask GP to see patient to discuss management as per local guidance.
- Advice should be sought for those with ASSIGN scores over 20, or hypertension or hyperlipidaemia less than optimally controlled.

3.2. Cardiovascular High-risk situations - Presence or risk of arterial thromboembolism (ATE)

In the following situations, patients will need immediate specialist care or advice:

- Arterial thromboembolism - current arterial thromboembolism, history of arterial thromboembolism (e.g. myocardial infarction) or prodromal condition (e.g. angina pectoris)
- Cerebrovascular disease - current stroke, history of stroke or prodromal condition (e.g. transient ischaemic attack)
- Known hereditary or acquired predisposition for arterial thromboembolism, such as hyperhomocysteinaemia and anti-phospholipid antibodies (anticardiolipin-antibodies, lupus anticoagulant)
- New onset of migraine with focal neurological symptoms.

Urgent advice sought for those with a high risk of arterial thromboembolism due to multiple risk factors (see section 4.4) or to the presence of one serious risk factor such as:

- Diabetes mellitus with vascular symptoms
- Severe hypertension
- Severe dyslipoproteinaemia.

4. The following are NOT required:

- Osteoporosis screening (bone loss only happens with prolonged GnRH treatment without added-in oestrogen, which should not happen)
- Routine measurement of estradiol levels
- Prolactin measurement
- PSA screens
- Screening for meningiomas and prolactinomas (which may be linked to cyproterone acetate usage) as these are exceptionally rare.

Also note that the reference range for some tests will differ from the standard range for that gender. Please see: Laboratory tests with gender-specific reference ranges (excluding hormones).

Test	Frequency	Abnormal result	Action if abnormal result
Creatinine and electrolytes	Annual – ONLY if taking spironolactone		GIC will monitor but for incidental findings, stop medication and seek advice
LFTs	6 monthly – ONLY if on cyproterone		GIC will monitor but for incidental findings, seek advice
BP and smoking advice	Annually or biannually	If hypertensive, treat at threshold for diabetes or target organ damage	Seek advice if severe / poorly controlled hypertension
Cardiovascular risk assessment	See comments above: ASSIGN score 5 yearly (age 40-55) and 3 yearly after that. *Use male gender for risk calculation*	Treat stage 1 hypertension and provide lifestyle advice. Advise of increased risk	The GIC will advise practices if ASSIGN score >20
VTE	Risk assessment at commencement of treatment and if new diagnosis or high-risk situation develops throughout treatment (see section 2 above)		Stop oestrogen and seek immediate advice. Note that VTE is especially associated with oral preparations
New onset active liver disease or malignancy	Throughout duration of treatment	This includes: 1. Presence or history of severe hepatic disease, e.g. active viral hepatitis and severe cirrhosis, as long as liver function values have not returned to normal 2. Presence or history of liver tumours (benign or malignant)	Inform the GIC. Please note that different blood reference ranges may apply and please see Lothian laboratory recommendations
Screening	Advise: breast and abdominal aortic aneurism screening and prostate awareness		NHS Inform provides transgender screening advice

Cautions, contraindications - Refer to current Summary of Product Characteristics: www.medicines.org.uk

Fertility, Pregnancy and Lactation

Refer to current Summary of Product Characteristics: www.medicines.org.uk for full detail.

Vaccination

Adverse effects - Refer to current Summary of Product Characteristics: www.medicines.org.uk for full detail.

Drug interactions - Refer to current Summary of Product Characteristics: www.medicines.org.uk for full detail.

The presence of this SCA does not compel a primary care prescriber to prescribe if they feel that it is out with the scope of their competencies (as per GMC guidance on safe prescribing) or resources, as ultimate responsibility lies with the prescribing, not the recommending, clinician.

For office use only:

Approved by the General Practice Prescribing Committee (GPPC) on 10th September 2024. Minor changes (email address update and correction of broken hyperlink) approved January 2025.

[i] ESHRE Guideline Group on POI, Webber L, Davies M, Anderson R, Bartlett J, Braat D, Cartwright B, Cifkova R, de Muinck Keizer-Schrama S, Hogervorst E, Janse F, Liao L, Vlaisavljevic V, Zillikens C, Vermeulen N. ESHRE Guideline: management of women with premature ovarian insufficiency. Hum Reprod 2016; 31:926-937.

[ii] Cross-sex Hormones and Acute Cardiovascular Events in Transgender Persons A Cohort Study. Getahun, D. et al. Ann Intern Med. 2018;169:205-213. doi:10.7326/M17-2785.

SHARED CARE AGREEMENT

Name of medicine	*Masculinising Endocrine Treatment (Testosterone)*
Indication	*Gender dysphoria/incongruence after assessment at the GIC for over 18 year olds*

Version: 1.0 Approval date: **September 2024** Review date: **September 2027**

The Shared Care Agreement (SCA) is intended to facilitate the accessibility and safe prescribing of complex treatments across the secondary/primary care interface. It does not contain all of the relevant product information, which should be sought using the current British National Formulary and manufacturer's Summary of Product Characteristics. The SCA must be used in conjunction with the NHS Lothian Procedure for the Shared Care of Medicines, available here.

Roles and responsibilities

Chalmers Gender Identity Clinic (GIC) will undertake initial assessment and recommending establishment of treatment for all those seeking masculinising endocrine treatment. GPs will be asked to be undertake the prescribing and reporting of any issues to the GIC.

However, recall and monitoring will be undertaken by the GIC, who will also undertake any clinical review required. The GP will then be asked to prescribe accordingly. This has now been agreed with the Lothian GP Sub-Committee. It has also been agreed that GPs will undertake a pre-dose testosterone level for those on depot preparations (please see below for further detail) as a trough measurement is needed.

This document uses the term **trans men** to include trans men and non-binary people recorded female at birth using masculinising hormones in connection with gender dysphoria or incongruence. This guidance is for adults aged 18 and over.

Listed below are specific responsibilities that are additional to those included in the NHS Lothian Policy and Procedures for Shared Care. Please refer to the policy for core roles and responsibilities that apply to all Shared Care Agreements.

Consultant

INITIAL SPECIALIST ASSESSMENT - GIC:

- Baseline assessment, treatment counselling, gaining informed consent, and recommendation of initiation of treatment (communicated to GP to be prescribed). This will include consent for the unlicensed use of medications
- Provide information both to the GP and the patient outlining risks of treatment
- Patient - signed agreement with the specialist about use of unlicensed medications, copied to the GP
- Assess the need for contraception, and prescribe/refer accordingly (reproductive age)
- Monitoring (usually 3 monthly) for the first year (or until patient on a stable medication regimen)
- Communication with GP about any changes in treatment
- Referral for specialist interventions relating to gender reassignment and transitioning
- Referral for non-specialist interventions as suggested by the GIC (e.g. CMHT, weight management etc)
- Advise about changes in CHI
- Discussion of relevant screening programmes details available from national screening programmes (cervical for those with an intact uterus; breast – may not be required if mastectomy has been performed)
- Cardiovascular risk assessment: ASSIGN
- There should be no need for additional bone protection, except in the rare situation of someone having had gonadal removal who is not also taking hormonal therapy. Please note the advice about Vitamin D in Scotland and on standard osteoporosis management.

ONGOING CARE (SHARED)

The following will be organised by the GIC who will recall all patients annually:

- 12 monthly monitoring: FBC (Hb & haematocrit) for all on testosterone treatment
- Testosterone levels for those on transdermal treatment (2-4 hours after dosing)
- From age of 50, 5 yearly BP measurement and full lipid profile for ASSIGN
- For those on injectable testosterone a trough sample is required immediately prior to injection, and it has been agreed with the GP Sub-Committee that this will be done by the GP team giving the injection. In due course it is proposed there will be an electronic method of ensuring that this result goes to the GIC. In the interim the GIC will advise arrangements

which may be the use of a paper form with destination Chalmers Gender Identity Clinic for the result. The bloods required are testosterone and FBC.

GIC ANNUAL REVIEW:

The patient will be offered a review. This may be virtual with the option of Patient-Initiated Follow up (PIFU) with GIC if there are interim clinical issues, thereby retaining specialist clinical oversight:

- Review of response to treatment, as indicated;
- Review of all the blood results as above, and 5 yearly ASSIGN score in those aged over 50;
- Discuss and encourage healthy lifestyle in line with standard advice – smoking cessation, maintaining a healthy weight, drinking alcohol according to national guidance (maximum 14 units per week), exercising regularly and eating well. Further advice is available at: https://www.nhs.uk/live-well/
- Communicate any incidental findings
  Incidental blood abnormalities detected on baseline screening or follow up that are not related to gender issues or unrelated to proposed or current hormone treatment (ie neutropenia/neutrophilia): GIC will ask GP to repeat and manage as per local guidance
- Communicate outcome to patient and GP, including any changes in medication, or non-attendance for required checks when prescribing would be reviewed.

General Practitioners and primary care non-medical prescribers

GENERAL PRACTITIONER RESPONSIBILITIES:

Prescribing of gender affirming hormones as advised by the GIC and reporting of any issues to the GIC

- Undertake annual trough testosterone bloods and FBC for those on injectable testosterone medication (see above)
- Cervical screening as for standard guidelines (requires sensitive discussion taking into account the patient's dysphoria)
- Assess the need for contraception, and prescribe/refer accordingly (reproductive age)
- Prescribing of treatment as per GIC advice
- Inform the GIC if there is a new diagnosis of liver, breast or other hormone-dependent cancer
- Inform the GIC if there is a diagnosis of severe liver, renal or cardiac insufficiency, or new onset IHD (or other new cardiovascular diagnosis), diabetes or rheumatoid arthritis

Opportunistically encourage healthy lifestyle in line with standard advice – smoking cessation, maintaining a healthy weight, drinking alcohol according to national guidance (maximum 14 units per week), exercising regularly and eating well.

Patient, relatives, carers

To attend for monitoring as requested.

To keep the GIC updated of any change to their name, address or phone number.

Support and Advice for the GP and primary care non-medical prescribers

Support and Advice for the GP

The GIC can be contacted by health professionals only for advice via SCI Gateway for Chalmers Sexual Health Centre, Gender Identity, otherwise clinical advice is available by email at loth.gic@nhs.scot. Referrals are viewed weekly and we will answer any queries within 7 working days. For more urgent advice you can phone the service admin team on 0131 5361570.

Hormone therapies are recommended under the Endocrine and Fertility Preservation Guidance 2022, based on the Scottish Government Gender Reassignment Protocol 2012. This advice is regularly updated by the clinical network (NCGICNS) and the latest is available at Endocrine Guidance – National Gender Identity Clinical Network for Scotland

Hormonal therapy may be recommended after the initial assessment is completed and the Lothian approach to prescribing and monitoring is supported by a multidisciplinary expert team.

New Patients

Some people will have been assessed by, or had treatment from, a recognised NHS gender identity clinic and are new to Borders, Fife or Lothian (the areas served by the GIC). If they have been assessed by an NHS GIC (or specialist gender service whilst resident overseas) the GIC can provide email advice on ongoing treatment or see patients where that is necessary. The GIC is unable to prioritise patients who have accessed private treatment and recommends that they are advised to continue their engagement with their existing provider until the GIC has completed its assessment.
For those moving into Scotland, please advise about the procedures for changing CHI numbers
and enrolling in the relevant national screening programmes. CHI numbers are gender specific, the penultimate number of the CHI signifying female (even number) or male (odd number).

Key Information on the Medicine

Refer to current edition of the British National Formulary (BNF), available at www.bnf.org, and Summary of Product Characteristics (SPC), available at www.medicines.org.uk for detailed product and prescribing information and specific guidance.

BACKGROUND - TESTOSTERONE

The literature for use of masculinising hormones is limited, but continues to evolve, and this guidance will be amended as new evidence emerges. The research is hampered by confounding factors, and that historically a variety of hormone doses and preparations have been used. Many of the recommendations for monitoring come from American practice, often over-cautious in relation to the available evidence. There is some internationally recognised guidance for monitoring, but it too has limitations and the recommendations in this document reflect a pragmatic multi-disciplinary consensus view.

There is now a growing - and reassuring - evidence base around the safety of testosterone used for gender reassignment. This now demonstrates that generally the risks are those of (physiological) replacement therapy in men with hypogonadism, as are the monitoring requirements. There are no prospective trials assessing risk, but retrospective cohort studies indicate a probable small rise in some cardiovascular markers (such as non-calcified plaque) but not in cardiovascular events. The largest of these was well-validated, but involved a young population[i], so we suggest vigilance remains necessary in older groups and those with other cardiovascular risk factors until prospective evidence becomes clearer. However, any additional risks are small, particularly when compared with the baseline prevalence. We therefore recommend standard healthy lifestyle approaches, and ASSIGN scores in older age groups to optimise blood pressure and lipid management in lines with standard care. But this is not a clinical indication to limit or stop testosterone use. There is no evidence of raised VTE risk.

There are limited data on the long-term health risks of hormone treatment and patients should be made aware that this is the case and the importance of long-term monitoring. However, evidence strongly supports the use of interventions in gender dysphoria for better clinical outcomes when the emotional and psychological risk versus benefit to the patient is accounted for. Risks may change over the course of a lifetime and need to be reassessed where new morbidities become apparent. The majority of people currently using masculinising treatment are young.

This is an unlicensed use of testosterone (except for Sustanon®), so the Summary of Product Characteristics relates to use in non transgender men, in whom breast cancer, and current or previous liver tumours are listed as contraindications.

Most trans men will not require GnRH analogues with masculinising hormones. If this does happen, please refer to the feminising treatment guidance for further detail.

In particular there is NO indication for the following checks or screening:

- Cardiovascular risk assessment in those aged under 50
- Routine liver function testing
- Osteoporosis screening
- Pituitary tumours (there seems to be a small rise in somatotrophinomas, but these are excessively rare)
- Change of dose in older age.

There needs to be caution about prescribing with cardiovascular co-morbidity, but there will be an initial assessment of this made at therapy initiation. However, it is thought that overall, the additional risks brought by testosterone are very low in healthy individuals and that there only needs to be a further assessment made if the person acquires a significant new cardiovascular diagnosis or risk factor such as diabetes or rheumatoid arthritis. Currently, most people receiving testosterone therapy for gender transition are low risk because they are young.

Please note that the GIC can also provide email advice, available to professionals only.

Please note that NEITHER TESTOSTERONE NOR GnRH analogue treatments PROVIDE CONTRACEPTION.

Testosterone is teratogenic and so effective contraception is recommended where appropriate to prevent unintended pregnancy unless bilateral oophorectomy or hysterectomy has been undertaken. Neither testosterone therapy nor gonadotrophin releasing hormone (GnRH) analogues are contraceptive.

Suitable contraception:

- All progestogen only methods (Implant, injectable, progesterone-only pill)
- LNG IUD
- Copper IUD

All methods of emergency contraception (CU-IUD, ulipristal, levonorgestrel) can also be used.

NB Combined hormonal methods should not be used as estrogen counteracts masculinising effects of testosterone.

The Faculty of Sexual and Reproductive Healthcare (RCOG) provides guidance on contraceptive choices for transgender and non-binary people.

Exogenous testosterone:

- The most common side effect is polycythaemia with raised haematocrit (risk is related to peak testosterone levels, so more common with short-acting injectable preparations, less common with transdermal administration)
- Administration of any oily depot preparation can very rarely cause Pulmonary Oil Microembolism – POME. This can be avoided by injecting very slowly over two minutes
- The manufacturers advice is that it is contraindicated in those with severe cardiac, renal or hepatic insufficiency, or IHD
- May increase coumarin anticoagulant activity – *increased INR monitoring is recommended at times of dose changes.*

Indication

Treatment of gender dysphoria following assessment at the GIC.

Dosage and administration

Introduction & titration: - undertaken by the GIC, with advice to GPs about prescribing

- Tostran® 2%, 10 or 20mg (1 or 2 'presses')/day may be titrated up to 80mg (8 'presses')/day
  OR
- Testogel® 16.2mg/g, 20.25mg/day (1 press) may be titrated up to 60.75mg/day (3 presses)
  OR
- Testogel® 40.5mg/2.5g, ½ or 1 sachet, may be titrated up to 2 sachets/day
  OR
- Testogel® 50mg/5g, ½ or 1 sachet, may be titrated up to 2 sachets/day
  OR
- Testavan® 2% gel 23mg (1 press) may be titrated up to 69 mg/day (3 presses)
  OR
- Sustanon® by injection, 125mg every 2-4 weeks for 2-3 months, increase to 250mg every 2-4 weeks if tolerated and testosterone levels sub-therapeutic. This should be injected slowly over 2 minutes.

Testosterone undecanoate injections have a longer half-life than other preparations so can help stabilise the small number of people who are chaotic with their treatment.

After 6 months, or once stable, patients either continue on the treatment they are on or offered the following maintenance treatments.

Maintenance:

- Testosterone undecanoate 1000mg deep intramuscular injection over at least 2 minutes usually every 10-14 weeks according to GIC recommendations **OR**
- Transdermal testosterone according to GIC recommendations **OR**
- Sustanon® intramuscular injection 125-250mg (NOT in the deltoid) every 2-3 weeks according to GIC recommendations.

Oral testosterone preparations are **not** recommended.

Decisions to adjust doses should be undertaken by the GIC.

Monitoring **Introduction & titration:** - undertaken by the GIC, with advice to GPs about prescribing

- Tostran® 2%, 10 or 20mg (1 or 2 'presses')/day may be titrated up to 80mg (8 'presses')/day
  OR
- Testogel® 16.2mg/g, 20.25mg/day (1 press) may be titrated up to 60.75mg/day (3 presses)
  OR
- Testogel® 40.5mg/2.5g, ½ or 1 sachet, may be titrated up to 2 sachets/day
  OR
- Testogel® 50mg/5g, ½ or 1 sachet, may be titrated up to 2 sachets/day
  OR

- Testavan® 2% gel 23mg (1 press) may be titrated up to 69 mg/day (3 presses).
  OR
- Sustanon® by injection, 125mg every 2-4 weeks for 2-3 months, increase to 250mg every 2-4 weeks if tolerated and testosterone levels sub-therapeutic. This should be injected slowly over 2 minutes.

Testosterone undecanoate injections have a longer half-life than other preparations so can help stabilise the small number of people who are chaotic with their treatment.

After 6 months, or once stable, patients either continue on the treatment they are on or offered the following maintenance treatments.

Test Testosterone ***(if transdermal treatment)***	Annually	Normal: 8.6-29nmol/L	The GIC will action: standard advice is to recheck to for persistent elevation.
Testosterone trough levels ***(if parenteral treatment)*** ***GP Practice to undertake prior to injection***	Annually	Abnormal: < 9nmol/L or >15nmol/L	The GIC will action: standard advice is to defer next injection by 2 weeks; if persistently above 20nmol/L, dose review is required.
FBC (Hb and haematocrit) ***GP Practice to undertake prior to injection (alongside testosterone level)***	Annually	Abnormal: Haematocrit > 0.52	The GIC will action. The following is standard advice: there are often minor rises in haematocrit which can be ignored. Increasing injection interval or changing to transdermal preparation can be effective. Consider referral to haematology for assessment and rarely venesection. *PLEASE ENSURE THE MALE REFERENCE RANGE IS BEING USED –see gender-specific reference ranges for blood tests.*
INR	Increased monitoring at time of dose change if coumarin anticoagulants used		Adjust warfarin dose accordingly.
Cardiovascular health	Age <50, maximise opportunities to give healthy lifestyle advice. Age >50, 5 yearly ASSIGN score.		The GIC will advise treating blood pressure and adverse lipid profiles in line with standard national guidance. GPs are reminded to seek GIC advice if new onset cardiovascular disease, diabetes or other concern about significant new risk.
Screening	Consider that breast and cervical screening may still be needed.		For specific transgender advice, please see: national screening programmes

Cautions, contraindications - Refer to current Summary of Product Characteristics: www.medicines.org.uk

Fertility, Pregnancy and Lactation

Refer to current Summary of Product Characteristics: www.medicines.org.uk for full detail.

Vaccination

Adverse effects - Refer to current Summary of Product Characteristics: www.medicines.org.uk for full detail.

Drug interactions - Refer to current Summary of Product Characteristics: www.medicines.org.uk for full detail.

The presence of this SCA does not compel a primary care prescriber to prescribe if they feel that it is out with the scope of their competencies (as per GMC guidance on safe prescribing) or resources, as ultimate responsibility lies with the prescribing, not the recommending, clinician.

For office use only:

Approved by the General Practice Prescribing Committee (GPPC) on 10th September 2024. Minor changes (email address update and broken hyperlink corrected) approved January 2025.

[1] Cross-sex Hormones and Acute Cardiovascular Events in Transgender Persons A Cohort Study. Getahun, D. et al. Ann Intern Med. 2018;169:205-213. doi:10.7326/M17-2785.