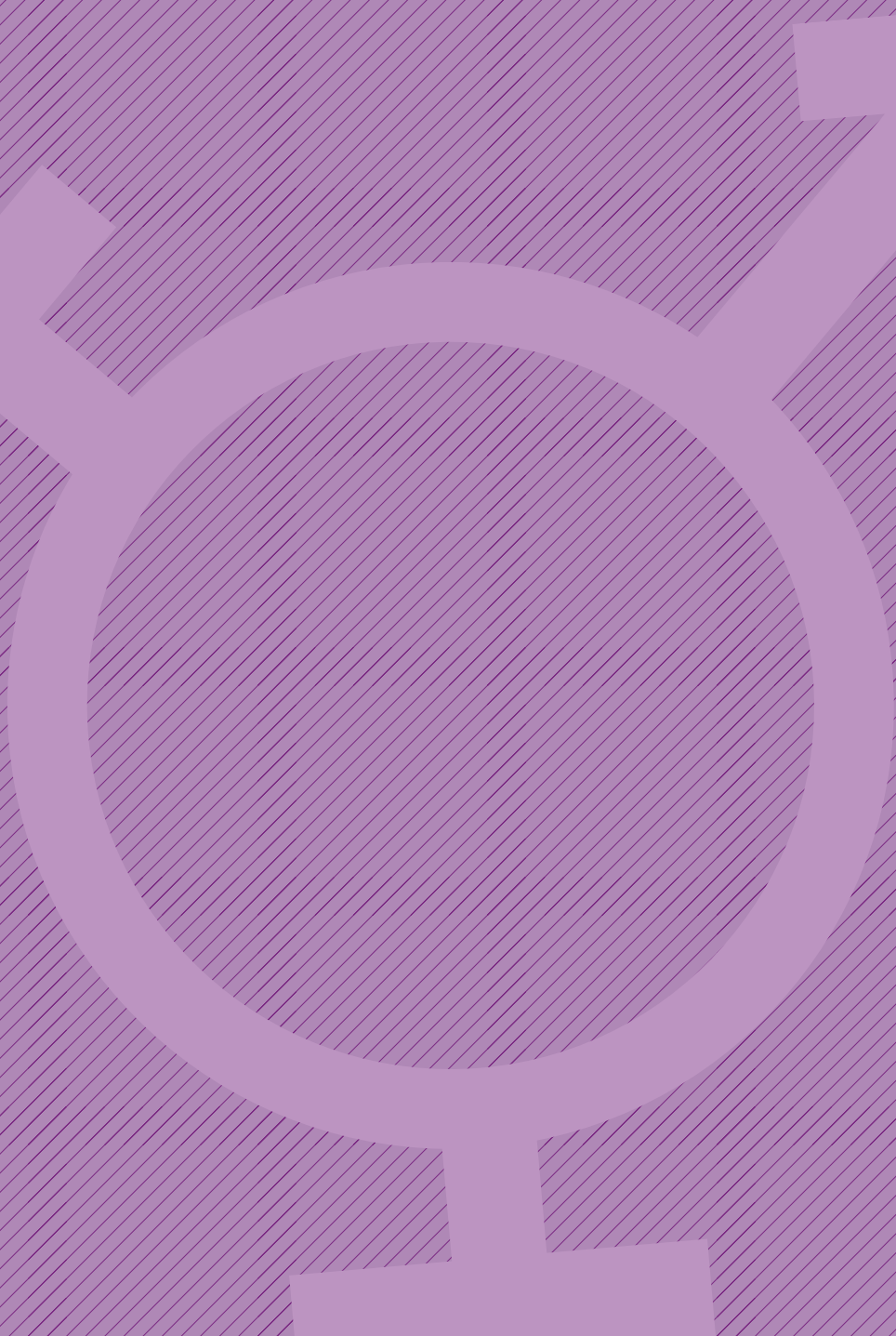


FENWAY  HEALTH

A large, light purple female symbol (a circle with a vertical line and a horizontal crossbar) is centered on the page. The background is a solid purple color with a fine, diagonal hatching pattern.

The Medical Care of Transgender Persons

FALL 2015

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01. General Philosophy

Fenway Health is a community health center that provides primary medical care, mental health care and addictions treatment, along with complementary services such as acupuncture, massage, optometry, dental care, nutrition counseling, and chiropractic care. The mission of Fenway Health is to enhance the wellbeing of the lesbian, gay, bisexual, and transgender communities and all people in our neighborhood and beyond. As part of that larger mission, the Transgender Health Program (THP) seeks to promote and support knowledgeable and comprehensive care to transgender and gender-nonconforming (TGNC) persons in an environment that is comfortable, safe, and affirming.

The THP operates with a multidisciplinary team of primary care providers and mental health clinicians who oversee and assist in the care of transgender clients so as to ensure a reasoned and holistic approach to the individual. As such, the team does not function as a gatekeeper, but is a facilitator and partner in the provision of excellent care with a broad perspective on the health of our patients. We acknowledge a spectrum of gender identity, and we support the varied and evolving expression of that identity in each person. Fenway Health and the THP seek to assist clients with their own personal exploration of gender and with the consequent decisions each patient might make regarding their individual gender identity and expression. We understand that this may or may not follow a standard linear progression from acknowledgment of identity to hormones and surgery, and that there are many individual paths with a range of goals and possible outcomes that may or may not include all or any medical interventions. We thus strive to collaborate with the individual patient in order to formulate treatment plans that are responsive to the particular and presenting concerns of that patient while ensuring a level of competence and responsibility to accepted standards of care of medical and mental health professionals.

These protocols acknowledge that hormonal treatment and surgery often play a vital role in the care of individuals with gender dysphoria and/or gender-nonconforming identities. We view hormonal treatment and pre-, peri-, and post-surgical care in the context of, and as a part of, overall primary care with a concern for the physical and mental wellbeing of each patient. Fenway Health also recognizes that when people undergoing gender transition/affirmation are deprived access to safe and affordable treatment, they may seek out other resources and options to achieve their goals of transition. Without professional assistance and guidance, these persons may place themselves at risk of great harm. Hormonal and other treatments for gender affirmation may have both desired and undesired physical and psychological effects, some of which may be irreversible, some potentially life-threatening. Therefore, it is the goal of Fenway Health and the THP to ensure that all patients are provided with the necessary information on risks and benefits of treatment. The prescribing provider must make an assessment of each patient's competency and ability to understand these risks and benefits and make an informed decision. We respect the individual's sense of self and agency, and will provide cross sex hormone therapy (CSHT) under an informed consent model. However, informed consent does not mean "hormones on demand", but requires that the prescribing provider, along with the patient, assess for and manage physical and mental conditions which might impact the safety and success of hormone therapy and surgical interventions. In keeping with the World Professional Association for Transgender Health's (*WPATH Standards of Care, Version 7*), we acknowledge the importance of mental health care for TGNC patients who may be struggling with gender dysphoria and the effects of stigmatization and discrimination. Many patients will have sought out mental health care as part of or in addition to their early exploration of gender identity. For some patients, mental health care may be an integral and prescribed part of their gender transition or affirmation. This care of the patient and the provision of CSHT will be achieved with a client-centered approach that balances individual needs within a harm reduction philosophy.

We also recognize that caring for TGNC patients is more than just the provision of CSHT and gender-affirming surgical procedures. Fenway Health and the THP are committed to providing comprehensive medical and mental health care with the knowledge and understanding of the special needs and challenges of TGNC persons, care that reflects current research in the field of transgender health.

The Protocols for the Care of Transgender Patients were developed by the THP clinical team after careful and extensive review of current research and in consultation with other medical and mental health professionals who have demonstrated experience and expertise working with TGNC persons. The protocols have been informed by the *WPATH Standards of Care, Version 7 (2011)*, and by the protocols of other facilities that specialize in the physical and mental health care of TGNC persons.¹ Fenway Health’s transgender care protocols attempt to reflect current knowledge and research on transgender health while acknowledging that the data and research are limited, often scientifically imperfect, and continuously evolving. In addition, no medications or other treatments are currently approved by the Food and Drug Administration (FDA) for the purposes of gender alteration and affirmation. The protocols thus rely on the collective experience of the medical and mental health providers at Fenway Health and other facilities. Given this reality, these protocols should not be viewed as a rigid or prescribed approach to transgender care, but as a dynamic document and guide which will continue to be updated and revised as knowledge, research, and experience progresses.

¹Acknowledgements to go Callen Lorde Health Center; UCSF Center of Excellence for Transgender Health; Vancouver Coastal Health, British Columbia; The Endocrine Society of North America; Tom Waddell Health Center; Sherbourne Health Centre; World Professional Association for Transgender Health (WPATH).

02. The Medical Care of Transgender Persons

Fenway Health seeks to promote the wellbeing of all its patients, regardless of gender identity. We refrain from pathologizing gender nonconformity, and we acknowledge that gender nonconformity is not synonymous with gender dysphoria, which is a “discomfort or distress that is caused by a discrepancy between a person’s gender identity and that person’s sex assigned at birth (and the associated gender role and/or primary and secondary sex characteristics.)” We recognize that not all patients with gender nonconformity will necessarily experience a sense of gender dysphoria that might impair their functioning or compel them to seek treatment that specifically addresses their gender.

For those patients who, at some point in their lives, do experience gender dysphoria, treatment options may include some or all of the following:

- non-medical changes in the person’s gender expression or role, possibly including binding or padding of breasts, hips or buttocks, penile tucking or use of prostheses.
- in-person or online support groups and services
- support services for family and friends
- changes in name and gender markers (socially and on identity documents)
- hair removal techniques, voice and communication therapy
- psychotherapy or counseling
- cross-sex hormone therapy or surgery to alter secondary sexual characteristics of the body.

We also strive to provide excellent preventative, acute, problem-focused, and continuing medical and mental health care to all TGNC persons, whether or not they may choose to pursue hormonal or surgical therapy as part of a gender transition.

03. General Requirements for Hormone Therapy

Candidate Requirements

Candidates for hormone therapy must be 18 years old and able to make and give informed consent for therapy.

Hormone treatment is expected to be life changing and will result in some irreversible effects; potentially serious complications of hormone therapy may occur. Because the use of medications for CSHT is considered to be “off-label”, all patients will be asked to provide signed consent for hormone therapy.

The informed consent for hormone treatment will include information on the intended benefits, potential risks, medication usage and the expected time-course of masculinizing or feminizing changes, as well as a realistic expectation of those changes. Additionally, patients will be informed of, and asked to provide signed consent regarding, both (a) the potentially irreversible effects of hormone treatment on reproductive capability and (b) the rights and options for preserving reproductive potential. (See attached forms.)

Some medical and mental health providers at Fenway Health do provide counseling and support as well as general medical care to gender non-conforming adolescents. Occasionally, older adolescents may be treated with the consent of their parent(s) or guardian(s). Currently, however, the hormonal treatment of adolescents who have not yet completed pubertal development remains outside the scope of medical practice at Fenway Health. Fortunately, Fenway providers and their adolescent patients have referral access to specialized providers in the area who may assume treatment with puberty-suppressing hormones and/or cross-sex hormones.

Patients with cognitive or psychiatric disorders or active substance abuse disorders may have difficulty understanding risks and benefits of gender affirming medical treatment and may present challenges around providing informed consent. Medical and mental health providers will work with the Transgender Health Clinical Team (TCT) to best educate and prepare these patients prior to CSHT and to assess the patient’s ability to provide consent.

Candidates for hormone therapy must demonstrate a consistent and persistent gender-variant identity that meets criteria for gender dysphoria as categorized by the DSM-5. If significant mental or medical health conditions are present, they must be reasonably well controlled.

Fenway Health uses an informed consent model that is patient-centered and focuses on educating and supporting providers in how to deliver necessary, safe, competent and effective care to TGNC patients, rather than on requiring TGNC patients to prove their health needs to the medical provider. The TCT provides the necessary support and education to Fenway Health providers, as well as providing support and resource information to Fenway Health patients. In some cases, providers may ask the TCT for assistance in evaluating a patient’s gender dysphoria and readiness for hormone therapy; this provides an additional level of personalized care planning that assures all aspects of a patient’s care are addressed adequately.

Provider Requirements

Medical Provider Requirements

The Medical Department provider, in either the role of a primary care provider (PCP) or consultant provider (if the patient has a PCP elsewhere), is responsible for the following:

- performs the recommended medical (including bio-psycho-social) screenings, examinations, and history-taking necessary to assess a patient’s appropriateness and readiness for CSHT
- reviews with the patient and obtains Informed Consent for Hormone Therapy and acknowledgement of Reproductive Rights
- answers questions the patient may have about CSHT and his/her/their individual health care or provides appropriate referrals for answers when indicated

- based on patient desires and appropriateness, prescribes CSHT based on this protocol and informs the TCT of patient's entry into care at Fenway Health
- provides appropriate and comprehensive follow up care, primary care services (in the case of a provider in a PCP role), or consultative services (in the case of a provider in a consultant role) throughout the patient's length of time in treatment at Fenway Health.

Behavioral Health Provider Requirements

Fenway Health does not categorically require that all patients undergo mental health evaluation or treatment by a mental health provider prior to starting CSHT. Some patients may have already engaged in some sort of mental health support or treatment prior to seeking CSHT.

The medical provider may determine at the time of initial evaluation that a patient has a mental health condition that is not reasonably well controlled. In these cases, the medical provider may seek additional information and support from the patient's current behavioral health provider (with the patient's express and signed consent) or make a referral to Fenway Health's Behavioral Health services for further evaluation. The Behavioral Health Specialist (BHS) for the provider's team and the TCT may assist in coordinating the patient's referral for Behavioral Health services as indicated. The medical provider will then work with the behavioral health provider in determining the patient's readiness for hormone therapy and may initiate hormone therapy when both the medical provider and the mental health provider agree that it is safe and reasonable to do so.

Some patients may benefit from ongoing supportive Behavioral Health care as they begin their gender affirmation with CSHT. Patients will be encouraged to continue in active therapy and treatment with their mental health provider(s) during the initial transition period in order to support a balanced and optimally healthy gender affirmation process and to address both anticipated and unanticipated psychosocial consequences of a physical transition. Those patients who are not currently engaged in mental health services may be referred to Fenway Health's Behavioral Health Department or may be provided assistance in finding an outside behavioral health provider who is competent in the care of TGNC persons when this additional supportive care is indicated.

Transgender Health Program Requirements

The Transgender Health Program (THP) is headed by the THP staff; Coordinator of the THP, the Medical Director of the THP, and THP Patient Advocate, along with the Associate Director of Behavioral Health. The THP meets weekly as an extended Transgender Health Clinical Team (TCT) to provide consultations on treatment and ongoing training and education in transgender health care issues. The TCT is composed of members of both the Medical and Behavioral Health Departments at Fenway. Consultations may include assistance in assessment and formulation of approaches to problems arising in the care of individual patients, or to address more global concerns regarding TGNC health care, and to provide guidance in the management of patients living with gender dysphoria.

The THP Coordinator and THP Medical Director will assist in coordinating and conducting quality assurance activities looking at the healthcare of TGNC patients at Fenway Health.

04. Medical Requirements: Prior to Initiation of Hormone Therapy

All patients who will initiate hormone therapy will have a complete bio-psycho-social history and physical exam along with screening lab tests completed within the 90 days prior to initiation of hormone therapy. This evaluation may have been done by a provider outside of Fenway Health. The full record of that evaluation may be obtained and reviewed by the prescribing provider prior to the start of treatment, or the provider may conduct their own evaluation prior to the start of hormone treatment.

The purpose of the evaluation is to obtain a history of the emergence of patient's gender identity and to assess for gender dysphoria as well as to assess for the presence of any absolute or relative contraindications to hormone therapy or conditions that might impact and/or complicate decisions around hormone therapy.

The initial assessment will generally require 2 to 3 appointments with the prescribing medical provider. Hormone therapy may be initiated at the second or third appointment as judged appropriate by the provider in collaboration with the patient. In some cases, referral to other medical or behavioral health providers, or optimizing management of other medical conditions, may be deemed necessary prior to initiating hormone therapy.

The subjective medical evaluation should include:

- History of patient's realization and understanding of gender identity and gender dysphoria with a discussion of the desire for cross-sex hormone therapy and goals for hormone therapy and other gender affirming therapies.
- Detailed past medical history (PMH), assessing for coronary artery disease or cerebrovascular disease, arterial or venous thromboembolism or /pulmonary embolism, liver disease, hypertension, diabetes, breast or uterine cancer, erythrocytosis, pituitary adenomas, HIV testing and/or infection, other STDs.
- Family History of any cancer, cardiovascular disease, diabetes, blood clotting disorders or liver disease.
- Documentation of current or past prescribed and unprescribed hormone use as well as any history of injectable silicone or other body modifications.
- Social history, including an assessment of social support, history of current employment and significant activities, and discussion of how the patient foresees transitioning in these environments and contexts. At least a brief sexual history should be obtained.
- Mental Health History, specifically any history of major Depression or Bipolar Disorder, Psychosis, Impulse Control Disorders, substance use and abuse. Any past history of sexual, physical or emotional abuse or trauma should be elicited, though it may not be necessary to explore this fully in the initial assessment. Document past or present Mental Health treatment with counseling, psychotherapy and/or psychotropic medications.
- Add the chart marker "THP" to the EHR patient Problem List. Other chart markers may be added to assist in the tracking and provision of health maintenance services.

Physical Exam should include:

- Vital signs
- Complete physical examination. Breast and genital examination is not required for the initiation of hormone therapy, but its importance in screening for health problems and a plan for future examination and evaluation should be discussed; the physical exam should always follow a patient centered approach, keeping in mind that some patients may have extreme discomfort with their bodies and may find some elements of a physical exam traumatic
- Verify and add proper ICD10 Code F64._(1, 2, 8, 9) in the Problem List if present
- Verify and add additional medical ICD10 codes in the Problem List, when needed (e.g., E34.9, Q51.5, Z90.710)

Screening/baseline laboratory testing should include:

For Transgender Males (FTM):

- lipid panel, complete blood count;
- consider fasting blood glucose and/or glycated hemoglobin and liver function tests, if patient's exam or history

suggest polycystic ovarian syndrome, diabetes, or prediabetes;

- Urine HCG if patient is at any risk for pregnancy
- Consider serum testosterone if history and exam suggest PCOS or other androgenizing condition.

For Transgender Females (MTF):

- lipid panel, basic metabolic profile (lytes, glucose, BUN/creatinine);
- consider liver function tests, if patient will be taking oral estrogen
- Baseline testosterone level is generally not necessary and will not impact hormone treatment; consider in MTF, if history and exam suggests hypogonadism.
- Baseline prolactin levels are only necessary for patients with a history of hyperprolactinemia or pituitary adenomas or who have been taking medications that might increase prolactin levels, e.g. anti-psychotics

For Transgender Males (FTM) and Transgender Females (MTF):

- Test for HIV, viral hepatitis (A, B and C), RPR, gonorrhea and chlamydia based on patient's assessed risk of exposure to STDs
- Other lab work may be considered based on the patient's history and physical and provider's clinical judgment

Evaluation by an endocrinologist is not necessary to begin cross-sex hormone treatment, but referral to specific specialists may be considered when history and physical along with provider judgment and comfort dictate.

Patients should understand that laboratory tests will continue to be monitored through the course of therapy and that they will be expected to maintain regular follow up visits, especially during the first year of hormone treatment.

05. Hormone Treatment Regimens

Transgender Men (FtM)

Hormonal transition for FtM patients and progressive masculinizing effects on the body are achieved by the administration of testosterone. Several forms are available to patients at Fenway Health. Testosterone is potent, and generally the effects in most patients are quite vigorous and remarkable.

Patients who desire a more androgynous presentation or less vigorous masculinization may be treated with low doses or limited courses of testosterone, but should be counseled that vocal changes, hair growth and other masculinizing effects are not easily tailored and individual patient response is not easily predicted.

Most healthy adults can be started on the usual adult dosage of testosterone; many providers will start at a half-dose and then quickly increase to a full dose at the first follow up visit or later depending on the patient’s response and goals for treatment.

Dosage should be adjusted based on cessation of menses and the progress of other masculinizing effects or side effects. Patients should avoid supraphysiologic levels, as the aromatization of excess testosterone to estradiol can cause feminizing effects.

In younger patients, and in patients with lower body mass, consider starting at lower doses and increasing gradually. These patients may do well at smaller than usual doses.

Anecdotal reports exist of a destabilizing effect on bipolar disorder, schizophrenia and schizoaffective disorder, as well as adverse mood changes in patients with a history of psychic trauma. In these patients, providers should ensure that their psychiatric state and treatment is stabilized prior to initiating testosterone, then start at lower doses and increase gradually.

See Appendix for a timeline of masculinizing effects.

TESTOSTERONE

Injectable	
Medication name(s)	<i>testosterone cypionate</i> (suspended in cottonseed oil) or <i>enanthate</i> (suspended in sesame seed oil) injected intramuscularly
Usual dose	100 mg IM weekly or 200 mg IM every 2 weeks
Starting dose	May start at 40-80 mg weekly and increase by 20 to 40 mg 2 to 4 weeks, maximum 400 mg every 2 weeks
Additional comments	Recent studies demonstrate that subcutaneous injection results in similar serum levels of testosterone and masculinizing effects and may be an option for some patients. Compounding pharmacies, such as Strohecker’s Pharmacy, may compound cypionate into sesame seed oil if there is any indication that the patient may have an adverse reaction to the standard cottonseed oil suspension.

NOTE: Patients should be referred to nursing for initial injections and for training on self-injection; they may subsequently self-inject at home.

Injectable	
Medication name(s)	<i>Long-acting injectable testosterone undecanoate (Aveed)</i>
Usual dose	750 mg IM initial dose, 750 mg IM at 4 weeks, then injected every 10 weeks thereafter
Additional comments	The FDA has approved this formulation only under a restricted prescribing scheme. This medication option is not yet available at Fenway Health.

Topical	
Medication name(s)	<i>Androgel</i> , 2.5 gm packet (25 mg testosterone), 5 gm packets (50 mg), 1% Pump delivering 12.5 mg per pump (actuation), 1.62% Pump delivering 20.25 gm per pump <i>Testim</i> 5 gm (50 mg) tubes <i>Axiron</i> 2% delivering 30 gms per dose
Usual dose	50 mg of testosterone applied daily, to upper arms or thighs
Starting dose	May start at 12.5 mg daily and increase by 12.5 to 25 mg every 2 to 4 weeks, maximum 100 mg daily (81 mg of the 1.62% formulation)
Additional comments	Compounding pharmacies may also make their own testosterone creams that are generally much less expensive to the patient than the brand-name formulations.

Topical	
Medication name(s)	<i>Androderm</i> patch, 2 mg or 4 mg
Usual dose	4 mg patch applied daily to upper arm, thigh, abdomen or back, change every 24 hours
Starting dose	May start at 2 mg, increase after 2 to 4 weeks, maximum 6 mg daily

Topical testosterone will provide a steadier level of hormone that is considered to more closely approximate normal physiologic testosterone levels than does IM administration. Consider starting patients initially on topical formulations, especially if there are concerns about the effects of fluctuations in hormone levels, or if the patient desires less vigorous and more gradual masculinization.

Patients must use caution in avoiding skin to skin contact with female partners or young children or pets. Patients should wash hands immediately after application. If skin to skin contact is anticipated, as with intimate sexual contacts, the area of application should be washed with soap and water; the majority of the dose will be absorbed from the skin within 4 to 6 hours of application.

Implantable Pellets	
Medication name(s)	<i>Testopel</i> , 75 mg (2 pellets generally equivalent to 25 mg of weekly IM testosterone)
Usual dose	6 to 10 pellets implanted every 3 to 6 months
Additional comments	Requires minor surgical procedure to implant pellets using a subcutaneous trochar with each application. There are Fenway Health providers trained in insertion procedure. This medication requires prior authorization from the insurance company.

OTHER MEDICATIONS THAT MAY BE USED WITH FTM PATIENTS:

Injectable	
Medication name(s)	<i>Depo-Provera</i>
Usual dose	150 mg IM every three months
Additional comments	May be used prior to starting testosterone to provide cessation of menses for those patients in whom menses is particularly troublesome, or used early in the course of testosterone therapy if menses does not cease with therapeutic levels of testosterone.

Oral/Sublingual	
Medication name(s)	<i>Finasteride</i>
Usual dose	1 mg to 5 mg by mouth daily
Additional comments	May be used to treat male pattern baldness that develops on testosterone treatment. May cause thinning or loss of other body hair and may interfere with clitoral enlargement.

Topical	
Medication name(s)	<i>Topical testosterone applied to the clitoris</i>
Usual dose	2-4% ointment in petrolatum base
Additional comments	This has been used in some FtM people to improve clitoral enlargement, though one study found no appreciable effect. DHT 10% cream has also been applied topically 3 times a day for clitoral enlargement; this cream must be compounded, but is currently difficult to obtain in the US.

Transgender Women (MtF)

Feminization is achieved primarily through the use of estrogen in doses that are several times higher than those used for contraception or post-menopausal treatment in natal females. Early treatment protocols used ethinyl estradiol until this formulation was shown to be associated with an exceptionally high rate of thromboembolic disease. Transdermal estradiol has been demonstrated to be much safer in regard to the risk of venous thromboembolism. Oral or sublingual estradiol also appears to be relatively safe. Oral conjugated estrogen (Premarin) has also been used, but now is generally more expensive and may incur a higher clotting risk; conjugated estrogens also cannot be measured in serum/blood.

Estrogen itself has an anti-androgen effect, but most treatment protocols also use a medication that interferes with the synthesis and/or biologic effect of testosterone. These androgen blockers help to counteract the masculinizing effect of endogenous testosterone and allow for lower doses of estrogen to be used.

ESTRADIOL

Transdermal	
Medication name(s)	<i>Topical patches</i> , multiple brands, multiple strengths including 0.05 and 0.1 mg/24 hours; topical gel also exists but is not often used because of the volume of gel that needs to be applied
Usual dose	0.1 to 0.4 mg (1 to 4 patches) applied once or twice a week (depending on the formulation)
Starting dose	Start at 0.05 or 0.1 mg, increase to 0.2 mg after 4 to 12 weeks; higher doses may be used in those patients who are not seeing signs of feminization after 3 to 6 months; remain at a starting or lower dose in patients at high risk for cardiovascular or thromboembolic disease
Additional comments	Estradiol patches should be the formulation of choice in those patients with known CAD or history of VT or in patients at high risk, e.g. older patients, hypertensive, hypercholesterolemia, diabetic; consider using in smokers.

Oral/Sublingual	
Medication name(s)	Tablets, 0.25, 0.5, 1 and 2 mg
Usual dose	4 mg by mouth daily, up to 6 mg daily
Starting dose	Start at 2 mg daily and increase to 4 mg after 4 to 12 weeks; consider increasing dose in those patients who are not seeing signs of adequate feminization after 3 to 6 months; remain at starting dose in higher-risk patients.
Additional comments	There is some study data in trans females that suggests that oral estradiol may be comparable in safety to transdermal formulation, though this is not clear. Patients should be encouraged to dissolve tablets sublingually to minimize first-pass effect on the liver.

Injectable	
Medication name(s)	Estradiol valerate (<i>Delestrogen</i>) 10 mg/ml, 20 mg/ml, 40 mg/ml
Usual dose	20 mg IM every 2 weeks, start at 5 to 10 mg weekly, max dose 40 mg every 2 weeks

Injectable	
Medication name(s)	Estradiol cypionate (<i>Depo-estradiol</i>) 5mg/ml
Usual dose	5 mg IM every 2 weeks, start at 2.5 mg every 2 weeks, max 10 mg every 2 weeks

There are no studies comparing benefits or risks of injectable estradiol with transdermal or oral formulations. IM injection does avoid first-pass effect on the liver, but patients might be at higher risk of estrogen side effects when at peak levels.

Anecdotally, injectable estradiol might possibly provide more vigorous and early breast development comparable to treatment with oral or transdermal estradiol, however, there is no empirical data to support this claim at this time.

Serum estradiol levels require an extended time to come to steady state with IM formulations that are absorbed slowly over several weeks.

There may be potential for an increased risk of intentional or unintentional overdosage and misuse of injectable estradiol. Therefore, injectable forms should only be used cautiously as first-line therapy, and might be used primarily in selected patients who fail to achieve adequate feminization with oral or transdermal formulations.

It is advised that all patients be started at the lowest recommended dose and that doses should be increased slowly. Consider monitoring serum estradiol levels every 3 months. Dosage may be adjusted by increasing or lowering dose or changing the dosing interval; IM estradiol may be given as infrequently as every 4 weeks.

NOTE: Patients should be referred to nursing for initial injections and for training on self-injection; they may subsequently self-inject at home.

ANTI-ANDROGENS

Oral/Sublingual	
Medication name(s)	<i>Spironolactone (Aldactone)</i> , 25, 50, 100 mg tablets
Usual dose	200 to 300 mg daily in a single or twice daily dose
Starting dose	Start at a dose of 50 mg daily and increase every 2 to 4 weeks to 200 mg daily, monitoring serum potassium; patients with inadequate feminization and/or serum testosterone levels above the female range may require higher doses.
Additional comments	Small and thin persons, persons with lower baseline blood pressure, persons on ACE-inhibitors/ARBs should be started at 25 mg daily with the dosage increased cautiously. Spironolactone directly inhibits testosterone secretion as well as inhibiting binding to the testosterone receptor; it may also exert an estrogenic effect of its own. It is inexpensive and generally well-tolerated. In North American protocols, spironolactone is the anti-androgen of choice.

Oral/Sublingual	
Medication name(s)	<i>Finasteride (Propecia, Proscar)</i> , 1 mg, 2.5 mg, 5 mg
Usual dose	1 to 5 mg by mouth once a day
Starting dose	Blocks the enzymatic conversion of testosterone to its more potent form, DHT.
Additional comments	Consider using in patients with male pattern baldness, in patients with heavy facial hair, or in patients who are unable to tolerate higher doses of spironolactone.

Oral/Sublingual	
Medication name(s)	<i>Dutasteride (Avodart)</i>
Usual dose	0.5 mg by mouth once a day
Additional comments	Has an effect similar to finasteride but does not come in a generic formulation, and so is more expensive.

PROGESTINS

Fenway Health and most other treatment protocols recommend against the routine use of progestins in the treatment of transgender women. Use of oral progestin with estrogen in the Women's Health Initiative Study on post-menopausal hormone replacement was associated with an increased risk of cardiovascular disease and breast cancer. These medications may also cause significant weight gain and negative mood changes.

Their benefit in hormonal gender affirmation is not well established. Anecdotally, progestins are reported to help improve breast development, especially development of the nipple/areola complex, but this outcome is not supported in small studies. Anecdotal increases in breast size may be due to progestin-stimulated weight gain.

Both intramuscular (Depo-Provera 150 mg IM every 120 days) and oral (Provera 2.5 to 10 mg daily or Prometrium 100-200 mg daily) formulations have been used.

If prescribing oral formulations, consider dosing cyclically only 10 days per month, to minimize doses and side effects, though some patients may experience pre-menstrual like symptoms with cyclic dosing.

OTHER MEDICATIONS

(NOTE: These are not used in Fenway Health's treatment protocol, however, patients may have questions or have used these meds prior to care at Fenway.)

Medication name(s)	<i>Cyproterone acetate</i>
Description	A progestin with potent anti-androgenic effect.
Additional comments	It is not approved for use in the US, but is used in many European treatment protocols. May have some thrombogenic effect of its own.
Medication name(s)	<i>Flutamide</i>
Description	An androgen receptor blocker.
Additional comments	Has been associated with significant liver toxicity.
Medication name(s)	<i>Goserilin acetate</i>
Description	A GnRH receptor agonist that down regulates production of sex hormones.
Additional comments	It has been used in study protocols in treating MtF patients and has been effective and well-tolerated. In the US, it is used primarily to treat prostate and breast cancers.
Medication name(s)	<i>Electrolysis</i>
Description	Female patients frequently will use <i>electrolysis or laser therapy</i> to manage facial and body hair that is not adequately decreased with hormonal therapy.
Medication name(s)	<i>Topical anaesthetic</i> , lidocaine 2.5%/prilocaine 2.5% cream (EMLA)
Description	May be applied prior to electrolysis to decrease discomfort with treatments.

Patients on Preexisting CSHT at Time of Care Initiation

Provider-Prescribed CSHT:

For patients who have begun hormone treatment prescribed by a previous health care provider or licensed medical facility and who are now transferring care to Fenway Health, the THP will seek to avoid disruption of ongoing treatment as well as ensure responsible and medically sound treatment and medical management. This is especially important for patients who have undergone any genital reconstructive surgery with gonadectomy and no longer produce endogenous sex hormones. Patients with previous CSHT will be asked to provide documentation of their previous treatment or sign a release form granting Fenway Health’s access to that documentation and record.

In most cases, hormone therapy should be continued without interruption, unless there are specific serious concerns on the part of the medical or mental health provider. The medical provider will ensure that the doses and formulations of hormonal medications are appropriate and safe for each individual patient. If the patient has been on prescribed hormone therapy for over a year, a full initial assessment of the appropriateness of hormone therapy may not be necessary. The medical provider will assess the need for appropriate monitoring examination and laboratory evaluation. The patient will be asked to sign a consent form for CSHT.

Self-Prescribed CSHT:

For patients who have been self-medicating and self-prescribing hormonal medications, the provider will first assess the safety and appropriateness of the medications the patient is currently using. In the interest of harm reduction, the provider may choose to continue the patient on an appropriate course of CSHT without interruption while the patient undergoes initial evaluation and assessment (“bridging therapy”). The patient must still be assessed fully with a complete history, physical examination, and laboratory evaluation. Referral for behavioral health assessment and management should be made as is appropriate and necessary for each individual patient. The patient will be asked to sign consent forms for CSHT.

06. Follow-up Care and Monitoring

Patients should be seen 1 month after initiating hormone therapy to assess for side effects and, if well tolerated, to increase to usual doses.

Patients will then be seen at 3 months, 6 months and 12 months.

After the first year on hormone therapy, patients should be seen every 6 months for the first 2 to 3 years of CSHT.

Patients who are stable on hormone regimens after 2 to 3 years and who are healthy without other medical issues may be seen every 12 months.

Follow up visits may be scheduled more frequently for patients with co-occurring conditions or who are at high-risk for potential adverse effects.

Procedures at follow up visits:

- Ensure that patient is using medication at the recommended dose; assess injection technique for problems if using an injectable medication. Assess for side effects of hormones. Ask about outside hormone use and any new medications.
- Measure weight and blood pressure and perform a directed physical exam.
- Assess both objective and subjective masculinizing/feminizing physical changes and patient satisfaction with transition. Patients may require re-education on the course and timing of and the individual variation in changes.
 - » Transgender men should experience cessation of menses within 3 to 6 months on hormone therapy; continued menstrual bleeding generally indicates the need for a higher dose of testosterone or concurrent treatment with progestin. (Note: Assess for sexual practices that may create small tears in the vaginal lining with spotting and may seem to the patient to be menstrual bleeding. Educate on effects of testosterone in thinning the vaginal lining and advise on use of viscous lubricants or other safer sex practices to reduce tearing, as appropriate.)
 - » In treatment surveys, many transgender women express dissatisfaction with breast development. This may be related, in part, to the size of the breast in proportion to the breadth of male chest and shoulders. Urge patients to wait for at least two years of estrogen treatment before considering surgical breast augmentation.
- Discuss psychosocial supports and experience of gender affirmation process. Assess patient's safety. Consider referral to support groups, case management or other services that will ensure or increase patient's safety and adjustment. The THP Patient Advocate and medical care team staff can assist patient with finding and connecting with community resources and support. Appointments with the THP Patient Advocate or other care team staff may be scheduled in coordination with medical provider visits.
- Assess mental health and any mood changes related to hormones. Consider referral for counseling or prescription for psychiatric medications if significant symptomatology. Consider modification of hormone dosing if needed.
- Strongly encourage patients to stop smoking, as necessary.
- Address the need/desire for document changes. Complete/write required medical documentation letters for amendment of legal documents. Patients may be referred to the medical care team staff or the THP Patient Advocate for assistance.
- Inquire about future plans for surgical procedures. Offer pre-operative direction and guidance (See appropriate section of protocols) and ensure that patients are medically stabilized and ready for surgery. The THP Patient Advocate or medical care team staff may assist providers and patients in finding a list of appropriate surgeons.

Laboratory monitoring

- Transgender Males (FtM)
 - » CBC, lipids, liver function tests at 6 months and then every 6 to 12 months (depending on age, personal and family hx and previous blood test results)

- » Consider glucose and/or Hgb A1C every 6 to 12 months in patients with suspected PCOS at baseline or with high risk of diabetes
- » Serum testosterone at 6 to 12 months after initiating therapy; levels may be checked within 2 to 6 weeks of a dosage change; consider yearly checks thereafter
 - Adequate testosterone dosing is chiefly assessed by clinically monitoring masculinizing physical changes, especially cessation of menses. Consider checking level if there is inadequate masculinization at 6 months. Consider monitoring to ensure that levels are not supraphysiologic, especially in younger and physically smaller patients.
 - Check level mid-way between injections. For patients using topical testosterone, levels may be checked at any time.
 - Target level is the mid-range of normal male levels, around 300 to 700 ng/dl.
- Transgender Females (MtF)
 - » For patients on spironolactone: check serum potassium and BUN/Creatinine 2 to 8 weeks after starting or changing dose
 - » Lipids, blood sugar, electrolytes, BUN/Creatinine at 6 months and then every 6 to 12 months (depending on age, personal and family history, and previous blood test results)
 - » Serum prolactin yearly

Reportedly, up to 20% of MtF patients will experience elevated prolactin levels while taking estrogens. Several cases of prolactinomas occurring in MtF patients on estrogen have been reported; one occurred 14 years after starting hormone therapy. Most protocols recommend only a single screening level 1 to 2 years into treatment or yearly levels for 3 years; further monitoring should be based on symptoms.

- Sex hormone levels
 - » Testosterone
 - Check serum testosterone at 6 months after stabilization of hormone dose or if inadequate feminization. Testosterone should be suppressed and in the mid-female range, 5–55 ng/dl.
 - Consider checking serum estradiol in patients on injectable estradiol, in patients at high risk for estrogen side effects, or in patients who are not experiencing adequate feminizing effects of hormone treatment.
 - » Estradiol
 - Levels should be checked midway between injections; in patients on transdermal or oral estradiol, levels may be checked at any time.
 - The target range is the mid-normal range for females, around 100–200 pg/ml, though higher levels within the normal female range may be tolerated, if the patient is at low risk for estrogen side effects. Lower levels close to this range may also be tolerated if the patient is feminizing well or has been on hormone treatment for over 3 years.

07. Health Maintenance Care

Mental Health

- Continue to screen for and be sensitive to possible mental health problems, depression, anxiety, and suicidal ideation.
- Ask patients about possible ongoing abuse, discrimination, violence, isolation, and assess social supports.
- Strongly consider referral to mental health specialist or psychiatrist if there are any concerns.

Surveys and empirical studies of TGNC people consistently report an increased risk of mental health problems and a high rate of suicidal ideation and attempts in transgender persons (between 30-60%), particularly in MtF individuals. In 2011, Asschemann, et al reported that the 51% increased mortality seen in their MtF patients was mostly due to causes not directly related to hormone treatment, chiefly suicide, drug abuse and HIV disease.

Most patients do report improvement in mental health after treatment for gender affirmation, though problems may still exist that impair functioning and have deleterious effects on mental health as indicated by a number of Asschemann's patients who committed suicide after successful completion of hormonal and surgical gender affirmation.

In FtM patients, especially at the beginning of therapy, injectable testosterone has been associated with mood lability.

In all TGNC patients, CSHT has been associated with a destabilization of bipolar disorder, schizophrenia, and schizoaffective disorder.

STD Prevention and Treatment

- Discuss sexual health with patients and ask about specific sexual practices related to the anatomy that is present.
- Assess for high-risk sexual behavior, abusive relationships, as well as injection drug use.
- Consider regular screening for HIV and STDs, as indicated. Test at all sites as dictated by sexual history and anatomy
- Vaccinate for HPV, Hepatitis A and Hepatitis B if not already done.

Although TGNC patients at Fenway have, thus far, evidenced very low rates of HIV (0.02% of our patient population) and other STDs, historically and in repeated observational studies, transwomen have had markedly high rates of HIV infection along with histories of high-risk sexual behavior, including involvement in sex work. MtF patients, in studies, also report relatively high rates of injection drug use, including injected hormones and injected non-medical silicone, in addition to street drugs.

Few studies have looked at rates of STDs and HIV in transmen, although data that does include FtM subjects also reports relatively high rates of STD and HIV infection in this population. Unprotected vaginal intercourse is reported as a significant risk factor for FtM patients contracting STDs and/or HIV.

Breast Health

Recent research (Brown & Jones, 2015) concludes that there is no increase in incidence of breast cancer than in the general population in CSHT treated TGNC patients.

Testosterone therapy has been shown to produce changes in breast tissue with decreased glandular tissue and increased fibrous tissue, which may affect the sensitivity and specificity of mammogram.

The natural history of breast development and breast cancer in the MtF population is not well understood. Studies fail to show significantly increased risk, but certainly, risk of breast cancer is related to the duration of estrogen exposure as well as other environmental and genetic factors. Cases of breast cancer in transgender women have been reported.

- In FtM patients who have not undergone chest reconstruction/mastectomy (including those who have had only breast reduction), screen as for natal women.

- In FtM patients who have had chest surgery, as some residual breast tissue may be present, perform yearly chest and axillary exam. (There is some empirical evidence that suggests breast cancer risk is reduced after chest reconstruction, however, the risk does not decrease to that of a natal male.)
- In MtF patients, consider screening mammogram starting at age 50 and if on hormone therapy for more than 5 years and with enough breast tissue to perform the mammogram screening. (In one study of breast cancer in transgender patients (Brown & Jones, 2015), the MtF patients all deceased due in part to late stage diagnosis of breast cancer, therefore, it may be necessary to provide additional breast cancer awareness education to transwomen who may not have ever received this information during natal development.)

Cervical Cancer

- FtM patients who have a cervix and who have had and/or continue to have any kind of receptive vaginal sex should have regular cervical Pap tests as per recommendations for natal women.
- Testosterone treatment may alter the cervical epithelium, mimicking dysplasia, so cytology request forms should note that the patient is on testosterone.
- For those patients who truly cannot tolerate speculum examination, consider self-administered vaginal swab testing for HPV. Those whose tests reveal the presence of HPV, should then be strongly urged to have a Pap test or to be referred for colposcopy. (The use of self-administered HPV swabs as a screen for cervical cancer is currently being examined in a study at the Fenway Institute.)
- With patients in whom the provider is confident that no receptive vaginal sex (including using fingers or “toys”) has ever occurred, the Pap test may be deferred after discussion of risks and benefits with the patient.
- MtF patients who have had vaginoplasty do not have a cervix and do not need Pap tests. Their vaginas are stratified squamous epithelium and not at risk for vaginal cancers.

Prostate Cancer

- MtF patients, even those who have undergone vaginoplasty or penectomy, still have a prostate gland and should continue to be screened for prostate cancer.
- Digital rectal examination of the prostate performed yearly after the age of 50; earlier as dictated by family hx of prostate cancer. (Note: after some genital reconstruction procedures the prostate may be palpable through the neo-vagina.)
- The USPSTF now recommends against routine screening PSAs; in any case, estrogen and anti-androgen treatment lowers PSA levels, and so the PSA cannot be used as a reliable screening test in MtF patients.

Endometrial and Ovarian Cancer

- Any transgender male with unexplained vaginal bleeding, especially if he initiated testosterone therapy at an older age, should be evaluated as would a natal female, with vaginal speculum and bimanual exam, pelvic ultrasound and/or endometrial biopsy.
- There is no good screening test for ovarian cancer; bimanual pelvic exam does not reliably detect ovarian cancer at an early stage. Transgender men with symptoms of pelvic pain or fullness or detection of a lower abdominal or pelvic mass, should be referred for pelvic imaging and gynecologic evaluation of possible ovarian cancer.
- It is recommended that transgender men undergo hysterectomy and oophorectomy after 5 years of hormonal treatment, if the patient no longer wants to consider having his own biological children through pregnancy or gestational surrogacy. Insurance coverage and the cost of the procedure remain an issue for many patients.
- Generally, testosterone treatment results in atrophy of the endometrial lining. A high rate of endometrial hyperplasia was found in one older study, but these findings have not been replicated in subsequent studies.

Reports exist of endometrial cancer in FtM patients, but these were patients who started hormone at a later date; quite possibly, cancer already existed prior to treatment. There have also been reports of unusual forms of endometrial and endocervical cancer. Some protocols have recommended regular progestin challenges until there is no withdrawal bleeding, but there is no data to support any benefit to this practice and it may cause undue emotional distress and mental health problems in some transmen.

Testosterone can cause polycystic changes in the ovaries of transgender males. PCOS is associated with an increased risk of endometrial cancer, but not ovarian cancer. There have been three cases of ovarian cancer reported in the literature in transgender males. It is not clear if testosterone treatment affects the rate of ovarian cancer. Some protocols have recommended yearly pelvic/uterine ultrasounds to assess the ovaries and endometrial lining, but there is no data to support such screening.

There are anecdotal reports of transgender males experiencing cramping lower abdominal/pelvic pain, sometimes quite severe, in the months following initiation of testosterone treatment. Some reports link this pain to sexual activity or orgasmic response while others seem to experience this pain without apparent antecedent. Evaluation is often unremarkable. The cause for this pain/cramping is not clear. Most cases are self-limited and will respond, at least somewhat, to NSAID therapy. Some patients may have pain that is persistent or severe enough to warrant referral to a gynecologic surgeon for possible hysterectomy.

Cardiovascular Health

- Patients should be screened and managed based on their cardiac risk factors and known history of cardiac disease or thromboembolic disease.
- Screen BP at each follow up visit and screen lipids on a yearly basis.
- Aggressively address risk factors, especially smoking.
- Transdermal estrogen in low doses should be the treatment of choice in MtF patients at high risk for or with known CAD or hx of thromboembolic disease. Also consider daily low-dose aspirin therapy for transwomen at high risk of cardiovascular disease.

Our information on the effects of hormone treatment in transsexual patients and its impact on cardiovascular and thromboembolic disease derives largely from uncontrolled cohort studies and extrapolated data on natal male and female populations, so the quality of the evidence is low.

Cardiovascular Risks in MtF Transwomen

In MtF patients, reports of greatly increased risk of thromboembolic events (but not increased mortality) are generally attributed to the use of ethinyl estradiol (EE) in early treatment protocols, however a rate of thromboembolic complications in 1 to 2 % of patients are still reported in European cohorts. (This may be related to the use of cyproterone acetate, which has some thrombogenic potential, as the preferred anti-androgen in these centers.)

The smaller but significant increased risk of cardiovascular events, strokes, and related mortality recently reported in some European cohorts also appears to be related, at least in part, to past ethinyl estradiol use. The risk of thromboembolic events in these studies occurred predominantly in the first 12 months of hormone use, and decreased significantly thereafter.

The use of transdermal estradiol appears, in several studies, to be much safer than oral estrogen treatment (EE and conjugated estrogens), and, in fact, the risk of thromboembolic complications may not be increased above that of natal females with use of transdermal estradiol.

Most studies do not distinguish between EE, conjugated estrogens and estradiol when reporting findings on patients using oral preparations, so it is difficult to assess the risk of oral forms of estradiol. There is evidence that oral estradiol may have no different impact on levels of clotting factors and coagulability than transdermal estradiol. Asking patients to dissolve their estradiol tablets sublingually, may help to partially avoid the first-pass effect on the liver, and so further limit risk.

There is no good data on the use of injectable estradiol on thromboembolic or cardiovascular events. Although it avoids the first-pass effect, it may result in peak serum levels of estradiol that could incur higher risk.

Estrogen treatment and androgen blockade have mixed effects on cardiovascular risk factors. MtF patients have increased body fat, with evidence for increased insulin resistance and higher levels of circulating insulin. Blood pressure may be increased, though generally not to a clinically significant degree. HDL cholesterol is increased and

LDL lowered, though the LDL may circulate in a more atherogenic form; triglycerides are increased.

In general, the number of cardiovascular events reported has been small. A 2011 report on a Swedish cohort reported twice the risk of cardiovascular mortality, but this amounted to only just more than 1 case per 1000 patient/years. In the Dutch cohort, the increased risk of cardiovascular morbidity may be explained by the use of ethinyl estradiol, as well as higher rates of smoking and higher baseline cholesterol levels.

Cardiovascular Risks in FtM Transmen

Testosterone treatment in FtM patients is associated with increased body weight and visceral fat, some increase in insulin resistance, increased triglycerides and lowered HDL cholesterol levels, as well as possible increases in blood pressure. However, no cohort data shows increased rates of cardiovascular events or mortality.

To some degree, this may be explained by the fact that the FtM patients in these cohorts tend to be younger and healthier at baseline; it may be that we have just not yet seen the effects of testosterone on an aging transmale population.

Testosterone treatment may increase the risk of sleep apnea, which can also impact cardiovascular health.

Diabetes

- Screen yearly, especially if family history of DM. Consider screening more aggressively in FtM with a previous hx suggesting PCOS.

Estrogen has been shown to increase measures of insulin resistance.

Studies on testosterone are mixed, but also generally demonstrate increased insulin resistance. There is no data that shows increased incidence of diabetes after hormone therapy. Recent data shows increased rates of diabetes in transmales and transfemales at baseline PRIOR to initiation of hormone therapy; this may be due to higher rates of screening, however.

Musculoskeletal Health

- Consider bisphosphonate therapy in FtM patients who have other risk factors for osteoporosis or in any patient who has stopped taking hormone therapy after extended use, especially if the patient has had a gonadectomy in the past.
- Perform bone density screening:
 - » On FtM patients beginning at age 50 if on testosterone for more than 10 years
 - » On FtM patients beginning at age 60 if treated with testosterone for shorter periods
 - » MtF patients who have remained on hormone therapy and have no other risk factors DO NOT need bone densitometry screening. DO screen any MtF patient who has stopped hormone therapy after extended use.
- Testosterone treatment can cause weakening of tendons. Advise FtM patients who are beginning weight training programs to start at low weights and increase weight slowly

In most, though not all, studies that look at bone density, MtF patients on estrogen generally have been shown to have decreased measures of bone resorption and preservation of bone density.

Conflicting results have been obtained in FtM patients on testosterone. It appears that bone density may be related to the adequacy of dosing and serum testosterone levels; it is thought that the aromatization of some testosterone to estrogen is what may help to preserve bone density. Gooren has suggested that serum LH, which was shown to be inversely related to bone density, may be used to assess the adequacy of testosterone dosing.

Extended hormone therapy suppresses endogenous sex hormone production, so all transgender patients should be encouraged to continue hormone therapy indefinitely to preserve bone health.

08. Pre- and Post-operative Care

It is not within the scope of these protocols to provide extensive information in regard to the procedures for gender affirming surgeries. However, PCPs should have basic knowledge about these procedures in order to help counsel patients in regard to timing of surgery and anticipated pre-, peri-, and post-op course and complications.

There are currently limited surgeons who perform Sexual Reassignment Surgery/Genital Reconstructive Surgery (SRS/GRS) in this country and outside the U.S. Often patients have limited pre-operative contact with their surgeons and travel at great expense and distance to access surgery, later trying to limit the time in hospital or returning home very soon after surgery. PCPs may be asked to see patients in the pre- and post-operative period and to help manage minor post-op problems.

Gender affirming surgeries, especially genital reconstruction procedures, are major surgeries that can require rigorous pre- peri- and/or post-operative care on the part of the patient. These surgeries can be emotionally and psychologically, as well as physically, challenging. The primary care provider should not only assess the patient's physical fitness for surgery, but also help the patient to prepare emotionally and psychologically by discussing realistic expectations for surgery, including the peri- and/or post-operative care that may be necessary. The patient should be able to ensure a clean and safe living environment at least through the several weeks that will be required for wound healing.

WPATH has set out standards of care for surgery including criteria for the initiation of surgical treatments. [See appendix 9.] The patient's insurance company will generally also set out criteria that are at least as stringent as WPATH standards. Patients using insurance to cover all or parts of surgery will need to consult with their insurance company in regard to requirements for pre-authorization for surgical procedures, e.g. letters of support that must be met in order to secure approval by the insurance company for coverage. Some support through the BHS Project Assistant or the THP Patient Advocate is available to patients to coordinate and access referrals for surgical approval applications.

Transgender Women (MtF)

Surgical options for transwomen may include:

- breast augmentation
- orchiectomy
- penectomy
- vaginoplasty/vuvloplasty
- facial feminization surgery
- tracheal cartilage shave
- implants, liposuction, lipofillers

WPATH SOC states that patients should be on hormone therapy and living in the preferred gender role for one year prior to genital reconstruction procedures.

Transwomen patients should be counseled to wait for at least 2 years after initiating hormone therapy before undergoing breast augmentation. This will allow proper sizing and contouring of the breast.

In consideration of the potentially increased risk of thromboembolism, oral or transdermal estrogen is usually stopped 2 weeks prior to surgery; intramuscular estrogen is stopped 4 weeks prior. Estrogen therapy is usually resumed one to three weeks following surgery when the patient is ambulating adequately.

Post-orchietomy, with or without other surgical procedures, patients will no longer require androgen blocking agents, spironolactone or finasteride.

Many patients, especially older patients and those with increased cardiovascular risk, can safely and comfortably decrease their estrogen doses (to one half the pre-op dose) after orchietomy. It is recommended that patients continue estrogen indefinitely, though, in order to preserve bone health.

Some patients, especially younger women, may experience symptoms related to the loss of testosterone (fatigue, decreased libido, etc.); serum testosterone levels are generally undetectable in these patients. Supplementation with very small doses of testosterone or with Estratest (esterified estrogen + methyl testosterone, 0.625/1.25mg or 1.25/2.5 mg taken orally each day) may improve symptoms.

The neo-vagina requires regular self-dilating in order to maintain its depth and patency. Beginning three to four weeks post-operatively, patients will be asked to dilate two to four times a day for the first several weeks, and then gradually reduce to once a day through the first few months post-operatively. Most surgeons recommend continuing regular dilation once or twice a week, indefinitely, even if the patient has regular penetrative penile-vaginal sex with a partner. Each surgeon will provide the patient with their own particular instructions for dilation.

A yellow or brownish vaginal discharge may be expected for up to 4 weeks post-operatively after vaginoplasty. Thereafter, brownish discharge or bleeding is usually due to granulation tissue along the incision lines. The primary care provider may use a speculum to visualize residual granulation tissue. Silver nitrate can be used to gently cauterize the granulation tissue usually with good effect.

Fistulas and wound infections may occur as distant complications of surgery. Partial wound dehiscence is not uncommon and generally heals in by secondary intent with acceptable aesthetic results.

The neovagina is most often constructed from the skin of the penis. Therefore, the lining of the vagina is squamous epithelium rather than mucosal. (Alternatively and less commonly, a section of bowel may be used as the neovagina.) A white discharge and some odor may be due to the sloughing of squamous epithelial cells. Patients who are bothered by this may use a dilute vinegar and water douche.

The pH and flora of the neovagina differs greatly from that of the mucosal natal vagina. There are no lactobacilli. Yeast infections are rare. Symptoms of bacterial vaginosis may occur; if it is necessary to treat, vaginal clindamycin is the treatment of choice.

A second procedure, labioplasty, may be performed to refine and augment the labia and/or clitoral hood. This procedure is not uniformly necessary or desired.

Transgender Men (FtM)

Surgical options for transmales may include:

- Mastectomy
- Chest reconstruction
- Hysterectomy/salpingo-oophorectomy
- Metoidioplasty
- Urethroplasty
- Clitoral free-up
- Phalloplasty
- Vaginectomy
- Scrotoplasty
- Implants (e.g., testicular, erectile), liposuction, lipofillers

Most patients will desire chest reconstruction if cost can be negotiated. WPATH SOC do not require hormonal therapy as a criteria for chest surgery; some insurance companies will require a proscribed amount of time on hormone therapy or an explanation for absence of CSHT and the primary care provider may be able to attest that hormone therapy is not indicated.

Chest reconstruction is generally done with bilateral pectoral incisions and transplantation of the nipples. The nipple thus loses erotic sensation. Transmen with small breasts may be able to undergo a keyhole procedure that preserves the nerve supply to the nipple and erotic sensation.

Post-operative seromas and hematomas are not uncommon. Chest reconstruction is often done as out-patient/ambulatory surgery and patients are commonly sent home the same day. Drains are inserted post-operatively and general-

ly need to be removed within 10 days after the patient returns home. A patient may require that a drain be left in place a bit longer. Drains may be removed at the primary care provider's office. This is generally a very simple procedure.

It is fairly common that pectoral incisions will require revision and resection of dog ears at the ends of the incisions where the drains have been secured and after they are removed. Many surgeons include the cost of this revision in their initial fees though this may not be the case with MA insurance coverage laws and may require a secondary authorization petition. Some transmen experience the necrosis and loss of nipple grafts or discoloration of grafts post-surgically and these care situations will need to be managed in consultation with the surgeon.

WPATH SOC require a year of hormone therapy prior to any genital reconstruction surgery. MA insurance carriers will require multiple referral letters to pre-authorize GRS, and these may be coordinated through the BHS Project Assistant or the THP Patient Advocate.

Hysterectomy/salpingo-oophorectomy (TAH-BSO) may be covered by health insurance benefits when there is medical necessity established. In MA, medical necessity may be established through the diagnosis of gender dysphoria. Post-surgical healing and management of a TAH-BSO procedure is the same in a transmale as a natal female.

Urinary tract infections and urethral fistulas and constrictions are not uncommon after metoidioplasty or phalloplasty with urethral lengthening. Consultation with the operating surgeon or a urologist familiar with treating transmen is often necessary.

With phalloplasty, in addition to the neophallus surgical site, one or more donor sites from tissue grafting may also need to be managed for post-operative care and wound healing. The patient may have nerve impairment or permanent loss of protective sensation in the donor sites and/or in the neophallus depending on the particular GRS procedure used.

Typically a TAH-BSO is performed prior to or along with metoidioplasty or phalloplasty, but this is not always the case. A patient with apparent male genitalia may thus still retain their uterus and cervix or ovaries. These natal organs need to receive routine and preventative care if they are still intact. The provider may need to ask directly about which organs may have been retained in any GRS procedure.

Vaginectomy/Colpocleisis is performed by some by some but not all GRS surgeons as part of a metaoidioplasty or phalloplasty. Wound healing and care may be difficult for some patients post-operatively due to the location of the wound and possibly as a result of flexibility or access complicating factors for the patient to reach the area for adequate care.

Scrotoplasty may include surgically implanted tissue expanders. The pt may require the PCP or nursing staff to inject sterile saline solution into these expanders weekly until the next stage of GRS may be completed and testicular implants placed.

Testicular implants may erode through the skin and be extruded by the body. The patient and provider may need to consult with the surgeon to manage the wound and to plan for corrective surgery.

Erectile implants in a neo-phallus (phalloplasty) may not be able to be placed for a year or more after the last GRS procedure has healed. The primary care provider may need to continue to assist the patient with new referrals for this device and in subsequent post-operative care. Some transmen experience the extrusion of the erectile implant from the neo-phallus over time and possible tissue breakdown or problems with the erectile device may need to be monitored in routine medical visits.

09. Appendices

- Appendices 1-227
Combined hormone consent forms for feminizing and masculinizing hormone therapy and consent regarding fertility options (Note: these are available in both English and Spanish and can be downloaded from fenwayhealth.org/transhealth)

- Appendices 3-4 33
Chart briefly displaying options for feminizing hormones, chart briefly displaying options for masculinizing hormones

- Appendices 5-6 35
Charts detailing the onset and timing of masculinizing and feminizing therapy

- Appendices 7-8 36
Potential side effects and complications of hormone therapy

- Appendix 9..... 37
World Professional Association for Transgender Health SOC criteria for initiation of surgery

A1. Informed Consent Form

Informed Consent for Feminizing Hormone Therapy

The use of hormone therapy for gender transition/affirmation is based on many years of experience treating trans persons. Research on hormone therapy is providing us with more and more information on the safety and efficacy of hormone therapy, but all of the long-term consequences and effects of hormone therapy may not be fully understood.

This informed consent asks you to consider the expected benefits of hormone therapy and the possible side effects of hormone therapy, so that you can decide, with your medical provider, if hormone therapy is right for you. By signing this form, you are stating that you have discussed the risks and benefits with your medical provider or a member of the medical team and that you understand how these benefits and risks apply to you personally.

Androgen (testosterone) blockers are used to decrease the amount and/or block the effect of testosterone on and reduce the male features of the body.

Estrogen (usually estradiol) is used to feminize the body; estrogens can also decrease the amount and effect of testosterone. Your medical provider will determine the form of estrogen (pills, patches, gels or shots) and the dose that is best for you based on your personal needs and wishes, as well as considering any medical or mental health conditions you might have.

Each individual person responds to hormone therapy differently, and it is difficult to predict how each person will respond. You agree to take the androgen blockers and/or the estrogen only as prescribed and to discuss your treatment with your medical provider before making any changes.

This consent form uses some medical terms and words for body functions and parts. If you do not understand a word or term, please talk to your provider about this.

The Expected Effects of Feminizing Hormone Therapy

The feminine changes in the body may take several months to become noticeable and usually take up to 3 to 5 years to be complete.

Changes that will be PERMANENT; they will not go away, even if you decide to stop hormone therapy:

- » Breast growth and development. Breast size varies, in all women; breasts can also look smaller if you have a broader chest.
- » The testicles will get smaller and softer
- » The testicles will produce less sperm and you will become infertile (unable to get someone pregnant); how long this takes to happen and become permanent varies greatly

Changes that are NOT PERMANENT and will likely reverse if hormone therapy is stopped:

- » Loss of muscle mass and decreased strength, particularly in the upper body
- » Weight gain. If you gain weight, this fat will tend to go to the buttocks, hips and thighs, rather than the abdomen and mid-section, making the body look more feminine
- » Skin will become softer and acne may decrease
- » Facial and body hair will get softer and lighter and grow more slowly; usually, this effect is not sufficient, and most women will choose to have other treatments (electrolysis or laser therapy) to remove unwanted hair
- » Male pattern baldness of the scalp may slow down or stop, but hair will generally not regrow
- » Reduced sex drive
- » Decreased strength of erections or inability to get an erection. The ejaculate will become thinner and watery and there will be less of it.
- » Changes in mood or thinking may occur; you may find that you have an increased emotional reactions to things. The effects of hormones on the brain are not fully understood. Some persons find that their mental health improves after starting hormone therapy.

Hormone therapy will not change the bone structure of the face or body; your Adam’s apple will not shrink; the pitch of your voice will not automatically change. If necessary, other treatments are available to help with these things.

_____ I have questions about the possible effects of hormone therapy.

_____ My medical provider or a member of the medical team has answered my questions about the effects of hormone therapy.

The Risks and Possible Side Effects of Estrogen Therapy

- » Loss of fertility (unable to get someone pregnant). Even after stopping hormone therapy, the ability to make healthy sperm may not come back. How long this takes to become permanent is difficult to predict. Some persons choose to bank some of their sperm before starting hormone therapy. Because the effect on sperm is hard to predict, if you have penetrative sex with a natal female partner, you or your partner should still use birth control (e.g. condoms).
- » Increased risk of developing blood clots; blood clots in the legs or arms (DVT) can cause pain and swelling; blood clots to the lungs (pulmonary embolus) can interfere with breathing and getting oxygen to the body; blood clots in the arteries of the heart can cause heart attacks; blood clots in the arteries of the brain can cause a stroke. Blood clots to the lungs, heart or brain could result in death.
- » Possible increased risk of having cardiovascular disease, a heart attack or stroke. This risk may be higher if you smoke cigarettes, are over 45, or if you have high blood pressure, high cholesterol, diabetes or a family history of cardiovascular disease.
- » Possible increase in blood pressure; this might require medication for treatment.
- » Possible increased risk of developing diabetes
- » Nausea and vomiting (like morning sickness in a pregnant woman), especially when starting estrogen therapy
- » Increased risk of gallbladder disease and gallstones
- » Changes in blood tests for the liver; estrogen may possibly contribute to damage of the liver from other causes
- » May cause or worsen headaches and migraines
- » May cause elevated levels of prolactin (a hormone made by the pituitary gland); a few persons on estrogen for hormone therapy have developed prolactinomas, a benign tumor of the pituitary gland that can cause headaches and problems with vision and cause other hormone problems
- » May worsen depression or cause mood swings
- » May increase the risk of breast cancer. The risk is probably higher than in natal men but lower than in natal women; the risk probably is related to how long you take estrogen therapy.

The Risks and Possible Side Effects of Androgen Blockers (Spironolactone)

- » Increased urine production and needing to urinate more frequently; possible changes in kidney function
- » A drop in blood pressure and feeling lightheaded
- » Increased thirst
- » Increase in the potassium in the blood and in your body; this can lead to muscle weakness, nerve problems and dangerous heart arrhythmias (irregular heart rhythm)

_____ I have questions about the risks of hormone therapy.

_____ My medical provider or a member of the medical team has answered my questions about the risks of hormone therapy.

_____ I would like to discuss ways to help me quit smoking.

You understand that

- » Smoking may greatly increase the risks of taking hormone therapy, especially the risk of blood clots and cardiovascular disease. If you smoke, you should try to cut back or quit. If you have other risks for blood clots or cardiovascular disease, your provider may ask you to quit smoking before you start on hormone therapy.

- » Taking estrogen in doses that are higher than recommended by your doctor will increase your risk of side effects and may not produce better feminizing effects.
- » You will need to stop taking hormones for a few weeks before and after any surgery.
- » Treatment with estrogen is expected to be lifelong; suddenly stopping estrogen treatment after you have been on it for a long time may have negative health effects
- » You may choose to stop taking hormone therapy at any time or for any reason. You are encouraged to discuss this decision with your medical provider.
- » Your provider may decrease the dose of estrogen or androgen blockers or stop prescribing hormone therapy because of medical reasons and/or safety concerns; you can expect that the medical provider will discuss the reasons for all treatment decisions with you.
- » Hormone therapy is not the only way that a person may appear more feminine and live as a female; your medical provider and/or a mental health provider can help you think about these other options.

You agree to

- » Take androgen blockers and/or estrogens only at the dosage and in the form that your medical provider prescribes.
- » Inform your medical provider if you are taking or start taking any other prescription drugs, dietary supplement, herbal or homeopathic drugs, or street drugs or alcohol so that you can discuss possible interactions with and effects on your hormone treatment
- » Inform your medical provider of any new physical symptoms or any medical conditions that may develop before or while you are taking hormone therapy and discuss the evaluation of these conditions; inform your provider if you think you are having bad side effects from the medications.
- » Keep regular follow up appointments; this may include appointments for mammograms and prostate exams
- » Have regular monitoring blood testing done; your provider will discuss with you what tests are necessary in order to monitor for potential harmful effects and to ensure that your hormone therapy is safe and effective

____ I have questions about my rights and responsibilities with taking hormone therapy

____ My medical provider has discussed my questions and concerns with me

By signing this form you acknowledge that you have adequate information and knowledge to be able to make a decision about hormone therapy and that you understand the information your medical provider has given you. Based on this information:

____ I choose to begin estrogen

____ I choose to begin taking androgen blockers

____ I do not want to begin hormone therapy

Patient's name on health insurance

Patient's preferred name, if different

Patient signature

Date

Provider name

Date

Provider signature

Date

A2. Informed Consent Form

Informed Consent for Masculinizing Hormone Therapy

The use of hormone therapy for gender transition/affirmation is based on many years of experience treating trans persons. Research on hormone therapy is providing us with more and more information on the safety and efficacy of hormone therapy, but all of the long-term consequences and effects of hormone therapy may not be fully understood.

This informed consent asks you to consider the expected benefits of hormone therapy and the possible side effects of hormone therapy, so that you can decide, with your medical provider, if hormone therapy is right for you. By signing this form, you are stating that you have discussed the risks and benefits with your medical provider or a member of the medical team and that you understand and accept how these apply to you personally.

Testosterone is used to masculinize the body, to reduce the female features and increase the masculine features. Your medical provider will determine the form of testosterone (shots, gels or creams, patches, implanted pellets) and the dose that is best for you based on your personal needs and wishes, as well as any medical or mental health conditions you might have. Each individual person responds to testosterone differently, and it is difficult to predict how each person will respond. You agree to take the testosterone only as prescribed and to discuss your treatment with your doctor before making any changes.

The Expected Effects of Testosterone Therapy

The masculine changes in your body may take several months to become noticeable and usually take 3 to 5 years to be complete.

Changes that will be PERMANENT; they will not go away, even if you decide to stop testosterone treatment:

- » The pitch of your voice becomes deeper
- » Increased growth, thickening and darkening of hair on the body
- » Growth of facial hair
- » Possible hair loss at the temples and crown of the head (male pattern baldness) with possible complete baldness
- » Increase in the size of the clitoris/phallus

Changes that are NOT PERMANENT and will likely reverse if testosterone treatment is stopped:

- » Menstrual periods will stop, usually within a few months of starting testosterone
- » Possible weight gain. If you gain weight, this fat will tend to go to the abdomen and mid-section, rather than the buttocks, hips and thighs, making the body look more masculine.
- » Increased muscle mass and upper body strength
- » Possible feeling of more physical energy
- » Skin changes, including acne that may be severe
- » Increased sex drive
- » Changes in mood or thinking may occur; you may find that you have a decreased emotional reaction to things and possible increased feelings of anger or aggression. Some persons find that their mental health improves after starting hormone therapy. The effects of hormones on the brain are not fully understood.

____ I have questions about the possible effects of testosterone

____ My medical provider or member of the medical team has answered my questions about the effects of testosterone

The Risks and Possible Side Effects of Testosterone Therapy

- » Possible loss of fertility; you may not be able to get pregnant after being on testosterone therapy for some time; how long this might take to be a permanent effect is unknown. Some persons choose to harvest and bank eggs before starting on testosterone therapy.

- » Testosterone is not reliable birth control, however. Even if your periods stop, you could get pregnant; if you are having penetrative sex with a natal male partner, you should discuss using some form of birth control with your medical provider.
- » If you do get pregnant while taking testosterone, the high levels of testosterone in your system may cause harm and even death to the developing fetus
- » Other effects of testosterone on the ovaries and on developing eggs are not fully known
- » Some trans men, after being on testosterone for a number of months, may develop pelvic pain; often this will go away after some time, but it may persist; the cause of this is not known
- » The lining of the cervix and walls of the vagina may become more dry and fragile; this may cause irritation and discomfort; it also may make you more susceptible to sexually transmitted infections and HIV if you have unprotected penetrative sex
- » The effects on the risk of breast, uterine and ovarian cancer is not known
- » Possible changes in cholesterol, higher blood pressure and other changes to the body that might lead to an increased risk of cardiovascular disease (heart attacks, strokes and blockages in the arteries)
- » Possible changes in the body that might increase the risk of developing diabetes
- » Increased appetite and increased weight gain from both muscle and fat
- » Increased risk of sleep apnea (breathing problems while you are sleeping)
- » Possible abnormalities in blood tests for the liver; possible worsening of damage to the liver from other causes
- » An increase in the hemoglobin and hematocrit (the number of red blood cells); if this increases to levels higher than is normal in males, it may cause problems with circulation, such as blood clots, strokes and heart attacks
- » Increased sweating
- » Weakening of tendons and increased risk of injury
- » Possible worsening or triggering of headaches and migraines
- » Possible increase in frustration, irritability or anger ; possible increased aggression and worsened impulse control
- » Possible worsening of bipolar disorder, schizophrenia and psychotic disorders or other unstable moods

_____ I have questions about the risk of testosterone treatment

_____ My medical provider or a member of the medical team answered my questions about the risks of testosterone

_____ I would like to discuss ways to help me quit smoking

You understand

- » Smoking cigarettes may increase some of the risks of taking testosterone therapy
- » Taking testosterone in doses that are higher than recommended will increase the risks of testosterone treatment; higher doses will not necessarily work better to masculinize the body; in fact, abnormally high amounts of testosterone can be converted to estrogen that may interfere with masculinization
- » Testosterone treatment is expected to be lifelong; suddenly stopping testosterone after a long time on the medication may have negative health effects
- » You may choose to stop hormone therapy at any time and for any reason. You are encouraged to discuss this decision with your medical provider.
- » Your provider may decrease the dose of testosterone or stop prescribing testosterone because of medical reasons and/or safety concerns; you can expect that the medical provider will discuss the reasons for all treatment decisions with you.
- » Hormone therapy is not the only way that a person may appear more masculine and live as a male; your medical provider and/or a mental health provider can help you think about these other options

You agree to

- » Take testosterone only at the dosage and in the form that your medical provider prescribes.
- » Inform your medical provider if you are taking or start taking any other prescription drugs, dietary supplements, herbal or homeopathic drugs, or street/recreational drugs or alcohol so that you can discuss possible interactions with and effects on your hormone treatment

- » Inform your medical provider of any new physical symptoms or any medical conditions that may develop before or while you are taking testosterone and discuss the evaluation of these conditions; inform your provider if you think you are having bad side effects from the testosterone
- » Keep regular follow up appointments; this may include appointments for Pap smears, pelvic exams and mammograms
- » Have regular monitoring blood testing done; your provider will discuss with you what tests are necessary in order to monitor for potential harmful effects and to ensure that your testosterone treatment is safe and effective

____ I have questions about my rights and responsibilities with taking hormone therapy.

____ My medical provider has discussed my questions and concerns with me.

By signing this form you acknowledge that you have adequate information and knowledge to be able to make a decision about hormone therapy and that you understand the information your medical provider has given you. Based on this information:

____ I choose to begin testosterone therapy ____ I do not want to begin testosterone therapy

Patient's name on health insurance

Patient's preferred name, if different

Patient signature

Date

Provider name

Date

Provider signature

Date

A3. Feminizing Hormones

ESTRADIOL

Transdermal	
Medication name(s)	<i>Topical patches</i> , multiple brands, multiple strengths including 0.05 and 0.1 mg/24 hours; topical gel also exists but is not often used because of the volume of gel that needs to be applied
Usual dose	0.1 to 0.4 mg (1 to 4 patches) applied once or twice a week (depending on the formulation)
Starting dose	Start at 0.05 or 0.1 mg, increase to 0.2 mg after 4 to 12 weeks; higher doses may be used in those patients who are not seeing signs of feminization after 3 to 6 months; remain at a starting or lower dose in patients at high risk for cardiovascular or thromboembolic disease.

Oral/Sublingual	
Medication name(s)	<i>Tablets</i> , 0.25, 0.5, 1 and 2 mg
Usual dose	4 mg by mouth daily, up to 6 mg daily
Starting dose	Start at 2 mg daily and increase to 4 mg after 4 to 12 weeks; consider increasing dose in those patients who are not seeing signs of adequate feminization after 3 to 6 months; remain at starting dose in higher-risk patients.

Injectable	
Medication name(s)	<i>Estradiol valerate (Delestrogen)</i> 10 mg/ml, 20 mg/ml, 40 mg/ml
Usual dose	20 mg IM every 2 weeks, start at 5 to 10 mg weekly, max dose 40 mg every 2 weeks

Injectable	
Medication name(s)	<i>Estradiol cypionate (Depo-estradiol)</i> 5mg/ml
Usual dose	5 mg IM every 2 weeks, start at 2.5 mg every 2 weeks, max 10 mg every 2 weeks

ANTI-ANDROGENS

Oral/Sublingual	
Medication name(s)	<i>Spironolactone (Aldactone)</i> , 25, 50, 100 mg tablets
Usual dose	200 to 300 mg daily in a single or twice daily dose
Starting dose	Start at a dose of 50 mg daily and increase every 2 to 4 weeks to 200 mg daily, monitoring serum potassium; patients with inadequate feminization and/or serum testosterone levels above the female range may require higher doses.

A4. Masculinizing Hormones

TESTOSTERONE

Injectable	
Medication name(s)	<i>Testosterone cypionate</i> (suspended in cottonseed oil) or <i>enanthate</i> (suspended in sesame seed oil) injected intramuscularly
Usual dose	100 mg IM weekly or 200 mg IM every 2 weeks
Starting dose	May start at 40-80 mg weekly and increase by 20 to 40 mg 2 to 4 weeks, maximum 400 mg every 2 weeks
Additional comments	Weekly dosing is recommended at initiation of hormone therapy, as this will result in lower peak and higher trough levels.

Topical	
Medication name(s)	<i>Androgel</i> , 2.5 gm packet (25 mg testosterone), 5 gm packets (50 mg), 1% Pump delivering 12.5 mg per pump (actuation), 1.62% Pump delivering 20.25 gm per pump <i>Testim</i> 5 gm (50 mg) tubes <i>Axiron</i> 2% delivering 30 gms per dose
Usual dose	50 mg of testosterone applied daily, to upper arms or thighs
Starting dose	May start at 12.5 mg daily and increase by 12.5 to 25 mg every 2 to 4 weeks, maximum 100 mg daily (81 mg of the 1.62% formulation)
Additional comments	Compounding pharmacies may also make their own testosterone creams that are generally much less expensive to the patient than the brand-name formulations.

Topical	
Medication name(s)	<i>Androderm</i> patch, 2 mg or 4 mg
Usual dose	4 mg patch applied daily to upper arm, thigh, abdomen or back, change every 24 hours
Starting dose	May start at 2 mg, increase after 2 to 4 weeks, maximum 6 mg daily

Implantable Pellets	
Medication name(s)	<i>Testopel</i> , 75 mg (2 pellets generally equivalent to 25 mg of weekly IM testosterone)
Usual dose	6 to 10 pellets implanted every 3 to 6 months

A5-6. Onset and Timing Effects of Hormone Therapy

Masculinizing Effects of Testosterone		
Effect	Onset (months)	Maximum (years)
Skin oiliness/acne	1-6	1-2
Fat redistribution	1-6	2-5
Cessation of Menses	2-6	
Clitoral Enlargement	3-6	1-2
Vaginal atrophy	3-6	1-2
Emotional changes		
Increased sex drives		
Deepening of voice	3-12	1-2
Facial/Body Hair Growth	6-12	4-5
Scalp Hair Loss	6-12	
Increased Muscle Mass & Strength	6-12	2-5
Coarser Skin/Increased Sweating		
Weight Gain/Fluid Retention		
Mild Breast Atrophy		
Weakening of Tendons		

* Masculinizing effects are shown in their general order of appearance.

** Permanent effects are indicated in red.

Feminizing Effects of Estrogens & Anti-androgens		
Effect	Onset (months)	Maximum (years)
Decreased Libido	1-3	3-6
Decreased Spontaneous Erections		
Breast Growth	3-6	24-36
Decreased Testicular Volume	3-6	24-36
Decreased Sperm Production	Unknown	Unknown
Redistribution of Body Fat	3-6	24-36
Decrease in Muscle Mass	3-6	12-24
Softening of Skin	3-6	Unknown
Decreased Terminal Hair	6-12	> 36

NOTE: Possible slowing or cessation of scalp hair loss, but no regrowth. No change in voice.

* Feminizing effects are shown in their general order of appearance.

** Permanent effects are indicated in red.

A7-8. Potential Side Effects and Complications of Hormone Therapy

Risks of Testosterone Therapy
Lower HDL
Elevated triglycerides
Increased homocysteine level
Hepatotoxicity
Polycythemia
Chronic Pelvic Pain
Unknown effects on breast, endometrial, ovarian tissues
Increased risk of sleep apnea
(Insulin resistance)
Infertility

Risks of Estrogen Therapy
Venous thrombosis/thromboembolism
Weight gain
Decreased libido
Increased triglycerides
Elevated blood pressure
Decreased glucose tolerance / risk of diabetes
Gallbladder disease
Breast cancer ?
Infertility

A9. World Professional Association for Transgender Health Criteria for Surgical Referrals

Criteria for Breast/Chest Surgery (One Referral)

Criteria for mastectomy and creation of a male chest in FtM patients:

1. Persistent, well-documented gender dysphoria;
2. Capacity to make a fully informed decision and to consent for treatment;
3. Age of majority in a given country (if younger, follow the SOC for children and adolescents);
4. If significant medical or mental health concerns are present, they must be reasonably well controlled.

Hormone therapy is not a prerequisite.

Criteria for Breast Augmentation (implants/lipofilling) in MtF patients

1. Persistent, well-documented gender dysphoria;
2. Capacity to make a fully informed decision and to consent for treatment;
3. Age of majority in a given country (if younger, follow the SOC for children and adolescents);
4. If significant medical or mental health concerns are present, they must be reasonably well controlled.

Although not an explicit criterion, it is recommended that MtF undergo feminizing hormone therapy (minimum 12 months) prior to breast augmentation surgery. The purpose is to maximize breast growth in order to obtain better surgical (aesthetic) results.

Criteria for Genital Surgery (Two Referrals)

The criteria for genital surgery are specific to the type of surgery being requested.

Criteria for hysterectomy and salpingo-oophorectomy in FtM patients and for orchiectomy in MtF patients:

1. Persistent, well-documented gender dysphoria;
2. Capacity to make a fully informed decision and to give consent for treatment;
3. Age of majority in a given country;
4. If significant medical or mental health concerns are present, they must be well controlled.
5. 12 continuous months of hormone therapy as appropriate to the patient's gender goals (unless hormones are not clinically indicated for the individual).

The aim of hormone therapy prior to gonadectomy is primarily to introduce a period of reversible estrogen or testosterone suppression, before the patient undergoes irreversible surgical intervention.

Criteria for metoidioplasty or phalloplasty in FtM patients and for vaginoplasty in MtF patients:

1. Persistent, well-documented gender dysphoria;
2. Capacity to make a fully informed decision and to consent for treatment;
3. Age of majority in a given country;
4. If significant medical or mental health concerns are present, they must be well controlled;
5. 12 continuous months of hormone therapy as appropriate to the patient's gender goals (unless hormones are

¹ This appendix material is taken directly from Coleman, E., Bockting, W., Boltzer, M., Cohen-Kettenis, P., DeCuypre, G., Feldman, J., ... Zucker, K. (2011). Standards of care for the health of transsexual, transgender, and gender-nonconforming people, version 7. *International Journal of Transgenderism*, 13, 165–232 doi: 10.1080/15532739.2011.700873

not clinically indicated for the individual).

6. 12 continuous months of living in a gender role that is congruent with the patient's identity.

Although not an explicit criterion, it is recommended that these patients also have regular visits with a mental health or medical professional (pp. 201-202).

Letters of Referral for Surgery

Surgical treatments for gender dysphoria can be initiated by a referral (one or two, depending on the type of surgery) from a qualified mental health professional. The mental health professional provides documentation—in the chart and/or referral letter—of the patient's personal and treatment history, progress, and eligibility. Mental health professionals who recommend surgery share the ethical and legal responsibility for that decision with the surgeon.

1. One referral from a qualified mental health professional is needed for breast/chest surgery (e.g., mastectomy, chest reconstruction, or augmentation mammoplasty).
2. Two referrals—from qualified mental health professionals who have independently assessed the patient—are needed for genital surgery (i.e., hysterectomy/salpingo-oophorectomy, orchiectomy, genital reconstructive surgeries). If the first referral is from the patient's psychotherapist, the second referral should be from a person who has only had an evaluative role with the patient. Two separate letters, or one letter signed by both (e.g., if practicing within the same clinic) may be sent. Each referral letter, however, is expected to cover the same topics in the areas outlined below.
3. No letter is required for hysterectomy/salpingo-oophorectomy or orchiectomy to be performed for reasons unrelated to gender dysphoria or due to other diagnoses.

The recommended content of the referral letters for surgery is as follows:

1. The client's general identifying characteristics;
2. Results of the client's psychosocial assessment, including any diagnoses;
3. The duration of the mental health professional's relationship with the client, including the type of evaluation and therapy or counseling to date;
4. An explanation that the criteria for surgery have been met, and a brief description of the clinical rationale for supporting the patient's request for surgery;
5. A statement that informed consent has been obtained from the patient;
6. A statement that the mental health professional is available for coordination of care and welcomes a phone call to establish this.

For providers working within a multidisciplinary specialty team, a letter may not be necessary, rather, the assessment and recommendation can be documented in the patient's chart (pp. 182-183).

F E N W A Y  H E A L T H

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