PROTOCOLS FOR THE PROVISION OF HORMONE THERAPY

CALLEN LORDE
COMMUNITY HEALTH CENTER

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Disclaimers

Disclaimer as to Protocols: These protocols are for general information only and should not be relied upon as medical advice. Each case is individual and should be subject to the review of the individual practitioners involved. The attached protocols, including all introductory materials and appendices, have been developed by and constitute the guidelines used by Callen-Lorde Community Health Center's medical and mental health providers providing primary care to transgender patients receiving hormone therapy. The protocols are guidelines only. They reflect our review of the available medical literature and our experience in providing this therapy, but are by no means definitive. They are not the result of scientific studies or clinical trials, and there are no medications that are FDA approved for hormone therapy. For all these reasons, no representations are made as to the propriety of their use in specific cases, and they may not be substituted for sound clinical judgment by the treating clinician.

Additional Disclaimer as to Informed Consents: The informed consent documents attached to the Protocols are provided only as examples. NO representations are made as to their applicability to or legal sufficiency for your agency. Accordingly, these documents should not be used by you without professional legal advice.

Guide to Using the Protocols

A Note on Age and Informed Consent

These protocols were written for use in patients 18 years of age or older. These protocols were not written with the specific endocrinological and psychosocial needs of younger patients in mind, nor do they address the legally complex nature of obtaining informed consent in minors. Therefore, these protocols should not be used to provide hormone therapy to a younger age group.

Hormones can be provided to patients over the age of 18 who cannot provide informed consent on their own, through the consent of a legal or court-appointed guardian.

A Note on the Specific Timing of the Interventions

We understand that every clinical setting operates a little bit differently and changes over time. The timing of these protocols – when appointments should be made, when bloodwork needs to be drawn in relation to appointments, etc. – was written with Callen-Lorde's current operations in mind. When adapting these protocols to a different setting, it may be more practical to keep these general principles in mind, rather than the specific timing:

1. When starting a new medication, start at half-dose.
2. Reassess the patient one month after initial prescription with blood work, history and physical evaluation before increasing the medication to full dose (prescribe only enough for one month).
3. Reassess the patient one month later at full dose.
4. Reassess the patient three months later.
5. Reassess the patient every six months to one year.
6. Maintain a harm reduction approach and be open to negotiation at every step.

General Philosophy and Vision

Callen-Lorde Community Health Center provides trans-affirmative health care by emphasizing partnership, education, and self-determination. We view treatment as a cooperative effort between patient and provider. We strive to establish relationships with patients in which they are the primary decision makers about their care, and we serve as their partners in promoting health. This partnership supports the patient's ongoing understanding of the risks and benefits of hormone therapy. By providing thorough education around hormones and general health, we also aim to enhance a patient's ability to make informed decisions about all aspects of their health. We believe patients who are well informed have a right to make their own decisions.

Callen-Lorde acknowledges that individuals of transgender experience have traditionally met discrimination in health care settings. We seek to provide trans-affirmative health care and strive to engage patients who would otherwise be alienated from the medical system or not get medical care at all. The mission of Transgender Health Services at Callen-Lorde is to provide comprehensive quality services to our patients of diverse gender identity and expression.

Callen-Lorde realizes that health care institutions discriminate against people of transgender experience by not conducting adequate scientific research on transgender health. We developed our protocols by compiling the collective knowledge of clinicians, patients, members of the transgender community, and related scientific studies. They are offered as guidelines for primary care for patients of transgender experience receiving hormone therapy. These guidelines should be seen as a starting point from which the patient and provider can arrive at a care plan appropriate to the patient's needs.

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Visit 1 or 2	Initial Medical Intake
Provider	Medical Provider
Goals of the Session	
	To introduce patients to the Callen-Lorde Transgender health services
	To collect baseline medical information
	To begin hormone therapy assessment
	To engage patients in a comprehensive primary care system

1. **Introduce patient to Callen-Lorde Transgender Health Services**
2. Provide and explain Transgender Health Resources Packet, available on Callen-Lorde's Transgender Health Services webpage. (www.callen-lorde.org/transhealth)
3. **Discuss hormones, risks and benefits, and elicit patient's expectations**
4. **Discuss possible diagnostic codes.** Some insurance companies may require a medical diagnosis in order to cover transition related services. This should be determined on a case-by-case basis
5. **Collect a complete medical history, including medical conditions that can be exacerbated by Hormone Therapy:**
   - Coronary Artery Disease
   - Deep Vein Thrombosis/Pulmonary Embolus
   - Embolic stroke
   - Liver disease
   - Pituitary adenoma
   - Uncontrolled Hypertension
   - Uncontrolled Diabetes
   - Breast or uterine cancer
   - Erythrocytosis
6. **Assess Health Care Maintenance (HCM) and update as needed, including:**
   - Tuberculosis screening
   - Immunization history, including Hepatitis A, Hepatitis B, Measles/Mumps/Rubella (MMR), Tetanus (Td/Tdap), influenza, pneumococcus, Human Papillomavirus (HPV)
   - Breast/chest Self-Exam
   - Testicular Self-Exam
   - Pelvic exam
   - HIV status and risk assessment
   - Assess need for colon cancer screening or baseline EKG
7. **Elicit mental health history including history of transgender identity, and screen for potential mental health concerns (see Appendix 3):**
   - Active psychosis
   - Cognitive impairment
   - Dementia
   - Suicidal/Homicidal ideation/Attempts

8. **Elicit social history:**
    - Alcohol use
    - Employment history
    - History of or current domestic violence or abuse
    - Illicit drug or street hormone use
    - Living situation
    - Sexual history
    - Gender identity history and prior transgender care
    - Social supports
    - Tobacco use
    - Silicone use
9. **Elicit family history:**
    - Cancer (i.e., breast, colon, ovarian, prostate)
    - Diabetes
    - Heart disease
    - Hypertension
    - Liver disease
10. **Elicit medications:**
    - Prescribed
    - Herbal
    - Over the counter
    - Street
    - Supplements
    - Prior hormone use
11. **Screen for allergies.**
12. **Draw labs:**
    - Complete Blood Count
    - Comprehensive Metabolic Panel (electrolytes, liver enzymes, lipids)
    - Hepatitis A, B and C panel
    - Syphilis screening

Note: Some guidelines recommend checking estradiol and testosterone levels at baseline and throughout the monitoring of estrogen therapy. We have not found a clinical use for routine hormone levels that justifies the expense. However, we recognize that individual providers may adjust their prescribing and monitoring practices as needed to comply with guidelines or when guided by patient need.

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13. **If HIV status unknown,** offer HIV testing.
14. **If indicated, ask patient for records of relevant previous or current medical care**, including HIV, mental health, and/or substance use/abuse treatment, as applicable.
15. **Arrange follow up:**
    - Supportive counseling and education
    - Medical visit

Note: As with all primary care patients, Primary Care Provider (PCP) can make direct referral to psychiatry, Mental Health, HIV counseling and testing, care coordination, or case management if there are any concerns

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Visit 1 or 2	Hormone Counseling & Education Session
Provider	Mental Health Provider, RN or Medical Provider
Goals of the Session	To counsel and assess patient ability to provide informed consent to Hormone Therapy To assess and initiate management of mental health complaints that might be adversely affected by Hormone Therapy To assess additional biopsychosocial needs of patient and offer related referrals/resources as indicated and/or requested

1. **Introduce purpose of Hormone Counseling & Education Session**
   - Counsel about the known risks and benefits of exogenous hormone therapy and confirm patient can provide informed consent to Hormone Therapy
   - Assess acute, active mental health complaints that may be adversely affected by Hormone Therapy
   - Assess and provide psychosocial supports and referrals as indicated.
   - Communicate assessment and findings to the medical provider who will be prescribing Hormone Therapy.
2. **Obtain informed consent to Hormone Therapy**
   - Assess that the patient's goals and understanding of Hormone Therapy match the general nature and purpose of Hormone Therapy
   - Assess patient's understanding of the physical, mental health, and social benefits and risks of Hormone Therapy
   - When applicable discuss alternatives to Hormone Therapy.
3. **Assess patient's day-to-day mood/mental health**
   - Counsel patient on the psychoactive effects of hormones:
     - Some mood/mental health problems such as depression and anxiety may be addressed by hormones, some symptoms are not
     - Some mood/mental health problems, including depression, anxiety and psychosis, may be exacerbated by hormones.
   - Gather information about patient's mood/mental health for the purpose of forecasting symptoms that may be intensified by Hormone Therapy:
     - If patient has untreated, non-acute symptoms, offer and refer patient to supportive mental health services (such as psychotherapy or psychiatry)
     - If patient has acute, untreated mood problems, discuss ways Hormone Therapy and mood problems can be managed safely. Guide patient to discuss these symptoms with the medical provider who will be prescribing Hormone Therapy.
4. Explore patient's social transition needs such as peer support, psychotherapy, identifying documentation changes, care coordination, and legal advocacy
   - As indicated, refer patient to internal and external resources, including Transgender Care Coordinator.

Note: Engagement in mental health care is not a requirement for hormone initiation.

5. **Elicit any additional questions the patient may have about Callen-Lorde's services, and/or physical or social transition.**
    - If patient intends to pursue gender confirming surgery, discuss ways to access surgical referrals as well as documentation required for surgery.
6. **Arrange an additional Hormone Counseling & Education Session visit if:**
    - Patient is unable to establish informed consent in the first session
    - Patient is interested in accessing additional support and/or counseling around Hormone Therapy
7. **Document visit in electronic health record**: including overall assessment of patient's ability to provide informed consent and any relative or absolute contraindications elicited during evaluation. Communicate directly with the prescribing provider about any serious concerns.

Visit 3	Medical Visit
Provider	Medical Provider
Goals of the Session	To complete medical/psychosocial assessment To initiate hormone therapy

Note: Depending on how much was covered in Visit 1/2, Visit 3 may cover more ground than is feasible in one appointment. If necessary to cover all the following elements, Visit 3 may be split into two appointments. Importantly, hormone treatment should not be initiated in a hormone-naïve patient until all the elements in Visits 1-3 are completed.

1. **Continue medical/psychosocial work-up**
2. **Review records from prior Primary Care Provider, if obtained.**
3. **Perform a complete physical exam.**

Note: The patient may postpone or refuse breast/chest or genital exam. If the patient refuses, renegotiate the time at which the exam will be done

4. **Review lab results and discuss implications of abnormal findings.**
5. **Continue Health Care Maintenance assessment from Visit 1.**
6. **If indicated, perform tuberculosis screening (PPD).**
7. **Give vaccines (Hepatitis A/B, HPV, etc) if indicated and desired.**
8. **Discuss smoking cessation if appropriate.**
9. **Arrange follow up medical visit within 4 weeks.**
10. **Discuss treatment plan.**
11. **Review the hormone therapy consent forms (see Appendix 1).**
12. **Document formal assessment of capacity to give consent in chart:**
    - Ability to communicate choice
    - Comprehension of clinical situation
    - Understanding of alternatives (hormones, surgery, no treatment), benefits, and risks
13. **If patient has capacity, have patient sign the informed consent for hormone therapy.**
14. **If patient signs informed consent, document that patient can begin hormone therapy.**
15. **Review Appendix 5 for available medications, potential side effects, and timeline of expected physical changes.**

16. Discuss with the patient the preferred route of hormones and prescribe one month of the appropriate regimen:

A. For Transgender women (MTF): The usual regimen is an estrogen + anti-androgen.

ESTROGENS: Prescribe one month of ONE of the following hormones:

Preferred Regimen

Oral Estrogen	Dose	Route & Frequency§	Amount	Refills
Estradiol (Estrace®)	1.0mg	Oral, twice daily	60 tablets	0
Injectable Estrogen	**Dose**	**Route & Frequency§**	**Amount**	**Refills**
Estradiol Cypionate 5mg/ml	0.5cc (2.5mg)	Intramuscular, every two weeks	1.0cc	0
Estradiol Valerate 20mg/ml	0.5cc (10mg)	Intramuscular, every two weeks	1.0cc	0

Alternate Regimen

Oral Estrogen	Dose	Route & Frequency	Amount	Refills
Premarin®	1.25mg	Oral, twice daily	60 tablets	0
Transdermal Estrogen	**Dose**	**Route & Frequency**	**Amount**	**Refills**
Estradiol Patch *	0.05- 0.1 mg	One patch topically, twice weekly	8 patches	0

* Transdermal estrogen may be preferred in some circumstances, e.g. age over 45, history of venous thromboembolic disease or cardiovascular risk factors. Although most patches are applied twice weekly, this may differ by product. Goal is to provide an initial dose of 50-100 mcg transdermal estradiol daily.

§ Some providers recommend administering oral estradiol sublingually or injectable estradiol subcutaneously.

ANTI-ANDROGENS: Prescribe one month of ONE of the following anti-androgens.

DHT-BLOCKERS: Some clinicians use dihydrotestosterone blockers as a primary anti-androgen, although they are less effective than either spironolactone or flutamide. DHT-Blockers may also be added to traditional anti-androgens to minimize androgenic hair loss.

Preferred Regimen

Oral Anti-Androgen	Daily Dose	Route & Frequency	Amount	Refills
Spironolactone	100mg	Oral, single or divided doses daily	1 month	0

Alternate Regimen

Oral Anti-Androgen	Daily Dose	Route & Frequency	Amount	Refills
Flutamide (Eulexin®)	125 mg	Oral, twice daily	60 tablets	0
Oral DHT-Blockers	**Dose**	**Route & Frequency**	**Amount**	**Refills**
Finasteride (Proscar®)	5mg	Oral, once daily	30 tablets	0
Dutasteride (Avodart®)	0.5mg	Oral, once daily	30 tablets	0

PROGESTERONE: Progesterone is not recommended as a part of the hormone regimen. It has not been shown to increase breast size, and may contribute to adverse outcomes. See Appendix 5 for dosing and adverse effects.

B. For Transgender men (FTM): The usual regimen is testosterone.

TESTOSTERONE: Prescribe one month of ONE of the following hormones*:

Preferred Regimen

Injectable Testosterone	Dose	Route & Frequency§	Amount	Refills
Testosterone cypionate or enanthate 200mg/ml§§	0.5cc (100mg)	Intramuscular or subcutaneous, every two weeks	1cc	0

Alternate Regimen

Transdermal Testosterone	Dose	Route & Frequency	Amount	Refills
Testosterone gel 1% (Androgel®, Testim®)**	2.5-5mg	One packet topically, daily	30 packets	0
Testosterone patch (Androderm®)	5mg	One patch topically, daily	30 patches	0
Testosterone undecanoate 250 mg/1 mL	750 mg	Intramuscular every 10-12 weeks; NOT FOR SELF INJECTION	3ml	

* A dihydrotestosterone blocker (e.g. Finasteride) at the usual male doses may be used in addition to testosterone to reduce androgenic hair loss.

**Low-dose transdermal testosterone may be insufficient to stop menses, consider addition of depot medroxyprogesterone (DepoProvera).

§ Some providers recommend administering injectable testosterone subcutaneously.

§§ Important: Commercially available testosterone cypionate is usually suspended in cottonseed oil. Testosterone enanthate is usually suspended in sesame oil. Enquire about allergies before prescribing these medications.

Agents not available in the USA (See Appendix 5)
Some clients may obtain hormones and anti-androgens from international pharmacies.

FTM:

- Testosterone undecanoate (oral) 160–240 mg/d
- Dihydrotestosterone 10% cream applied topically (to clitoris) 20mg three times daily. (Prescribed by some surgeons 3 months before metoidioplasty to increase clitoral size; however, insufficient data on efficacy.)

MTF:

- Cyproterone Acetate 50-150 mg/day oral (an anti-androgen)

17. **Give appropriate vaccinations**
18. **Order lab work for next medical visit (schedule 4 weeks after starting hormones)**
    - Liver enzymes
    - Electrolytes, if taking spironolactone
    - Complete blood count, if taking flutamide
19. **Arrange follow up**
    - If patient is taking injectable hormones and is not returning on the same day for the injection, first available nursing visit after filling prescription.
    - Nursing visit 2 weeks after first injection (if using injectable)
    - Nursing visit 4 weeks after first injection(if using injectable)
    - Medical visit in 5 weeks (all clients)

Visit 4	Nursing Visit
Provider	Nursing Provider
Goals of the Session	To provide patient with first injection of hormone therapy

1. **Ask patient preferred method of injection:** self-injection, injection by a significant other, friend, family or ally (SOFFA) or by nurse at Callen-Lorde. Testosterone undecanoate can only be administered in a medical facility due to risk of Pulmonary Oil Microembolism (POME) and anaphylaxis.

2. **If patient prefers nursing staff to inject, administer:**

   MTF clients

Injectable Estrogen	Dose	Route & Frequency
Estradiol Cypionate 5mg/ml	0.5cc (2.5mg)	Intramuscular, every two weeks
Estradiol Valerate 20mg/ml	0.5cc (10mg)	Intramuscular, every two weeks

   FTM clients

Injectable Testosterone	Dose	Route & Frequency
Testosterone Cypionate or Enanthate 200mg/ml	0.5cc (100mg)	Intramuscular, every two weeks

3. **If the patient chooses self-injection or by a SOFFA and is unfamiliar with self-injection**, initiate teaching of safe injection technique

4. **If the patient or a SOFFA is familiar with self-injection**, observe the injection being administered by the designated person and provide feedback. If the technique is sound, document approval for self-injection in the chart. If technique needs improvement, offer instruction.

5. **Arrange follow up Nursing Visit every 2 weeks** to continue teaching of safe injection technique to patient or SOFFA.

6. **Arrange for laboratory testing 4 weeks after initiation of hormones:**
   - Liver enzymes
   - Electrolytes, if taking spironolactone
   - Complete blood count, if taking flutamide

Visit 5 – 4 weeks after starting half-dose hormones	Medical Visit
Provider	Medical Provider and Nursing Provider
Goals of the Session	To perform initial assessment after the initiation of hormone therapy To continue hormone therapy To continue the provision of primary care

Nursing Provider:

1. **Check the patient's vital signs, including blood pressure.**
2. **Proceed with hormone injection after Medical Provider has reviewed the laboratory results** and authorized continuation of the treatment.
3. **If patient has chosen injectable hormones and is due for an injection:**
   - Ask if the patient is receiving injections from self or a SOFFA. If so, observe the injection technique.
   - If the technique is sound, document approval for self-injection in the chart.
   - If the technique needs improvement:
     - Offer instruction and support.
     - Schedule bi-weekly nursing appointments for further teaching and injections until the nursing provider assesses that the patient or SOFFA has learned the proper technique and can safely inject without supervision.

Medical Provider:

4. **Take history with focus on**
   - Patient's tolerance of hormones and anti-androgens
   - Any side effects patient may be experiencing
   - MTF client: Cessation of erections
   - FTM client: Cessation of menses
5. **Perform physical exam, including blood pressure.**
6. **Review lab results and discuss implications of abnormal findings.** Increase the dosage of hormones as follows and prescribe one month of:

A. For Transgender women (MTF):

ESTROGENS: Prescribe one month of ONE of the following hormones:

Preferred Regimen:

Oral Estrogen	Dose	Route & Frequency	Amount	Refills
Estradiol (Estrace®)	2.0mg	Oral, twice daily	60 tablets	0
Injectable Estrogen	**Dose**	**Route & Frequency**	**Amount**	**Refills**
Estradiol Cypionate 5mg/ml	1.0cc (5mg)	Intramuscular, every two weeks	5.0cc	0
Estradiol Valerate 20mg/ml	1.0cc (20mg)	Intramuscular, every two weeks	5.0cc	0

Alternate Regimen:

Oral Estrogen	Dose	Route & Frequency	Amount	Refills
Premarin®	1.25mg	Oral, two tablets twice daily	120 tablets	0
Transdermal Estrogen	**Dose**	**Route & Frequency**	**Amount**	**Refills**
Estradiol Patch	0.1mg	Two patches topically, twice weekly	16 patches	0

ANTI-ANDROGENS: Prescribe one month of ONE of the following anti-androgens.

DHT-BLOCKERS: Some clinicians use dihydrotestosterone blockers as a primary anti-androgen, although they are less effective than either spironolactone or flutamide. DHT-Blockers may also be added to traditional anti-androgens to minimize androgenic hair loss.

Preferred Regimen

Oral Anti-Androgen	Daily Dose	Route & Frequency	Amount	Refills
Spironolactone	200mg	Oral, in divided doses daily	1 month	0

Alternate Regimen

Oral Anti-Androgen	Daily Dose	Route & Frequency	Amount	Refills
Flutamide (Eulexin®)	125 mg	Oral, twice daily	60 tablets	0
Oral DHT-Blocker	**Dose**	**Route & Frequency**	**Amount**	**Refills**
Finasteride (Proscar®)	5mg	Oral, once daily	30 tablets	0
Dutasteride (Avodart®)	0.5mg	Oral, once daily	30 tablets	0

B. For Transgender men (FTM):

TESTOSTERONE: Prescribe one month of ONE of the following hormones:

Preferred Regimen:

Injectable Testosterone	Dose	Route & Frequency	Amount	Refills
Testosterone Cypionate or Enanthate 200mg/ml	1.0cc (200mg)	Intramuscular, every two weeks	2cc	0

Alternate Regimen:

Transdermal Testosterone	Dose	Route & Frequency	Amount	Refills
Testosterone gel 1% (Androgel®, Testim®)	5mg	One packet topically, daily	30 packets	0
Testosterone patch (Androderm®)	5mg	One patch topically, daily	30 patches	0

7. If the patient chose injection by herself or SOFFA and nursing approved the injection technique, prescribe:

Equipment	Amount
3cc syringe	#10
20-22G x 1.5" needles	#10
Alcohol prep pads	#100
needle disposal (sharps) container	#1

Note: other needle sizes and amounts may be more appropriate for some patients depending on personal preference and whether patients use different needles for drawing the medication and injecting.

8. Order lab work for next medical visit in 4-5 weeks:

- Liver enzymes
- Lipids
- Prolactin level, if MTF on estrogen
- Electrolytes, if taking spironolactone
- Complete blood count, if taking flutamide

9. Arrange follow up:

- **Nursing visit every 2 weeks, if requesting injections by nurse**
    - If the patient chose self-injection or injection by SOFFA, observe the injection being administered by the designated person and provide feedback. If the technique is sound, document approval for self-injection in the chart. If technique needs improvement, offer instruction.
- **Medical visit in 4-5 weeks**

Visit 6 - 4 weeks after starting full-dose hormones	Medical Visit
Provider	Medical and Nursing Provider
Goals of the Session	To perform assessment after a change of hormone therapy To continue hormone therapy To continue the provision of primary care

Nursing Provider:

1. **Check the patient's vital signs, including blood pressure.**
2. **Proceed with hormone injection after Medical Provider has reviewed the laboratory results** and authorized continuation of the treatment.
3. **If patient has chosen injectable hormones and is due for an injection:**
   - Ask if the patient is receiving injections from self or a SOFFA. If so, observe the injection technique. If the technique is sound, document approval for self-injection in the chart. If the technique needs improvement:
     - Offer instruction and support.
     - Schedule bi-weekly nursing appointments for further teaching and injections until the nursing provider assesses that the patient or SOFFA has learned the proper technique and can safely inject without supervision.
   - If the patient prefers nursing staff to inject, administer appropriate hormone and dose.

Medical Provider:

4. **Take brief history with focus on:**
   - Patient's tolerance of hormones and anti-androgens
   - Any side effects patient may be experiencing
   - MTF client: Cessation of erections
   - FTM client: Cessation of menses
5. **Review lab results and discuss implications of abnormal findings (see Appendix 4).**
6. **Discuss smoking cessation if appropriate.**
7. **Prescribe three months of ONE of the hormones and anti-androgens as outlined in Visit 5.**
8. **If the patient chose injection by herself or SOFFA** and nursing approved the injection technique, prescribe syringes and needles as outlined in Visit 5.
9. **If the patient is receiving injections from self or SOFFA** and the technique needs improvement, refer to nursing provider for further teaching and injections until the nursing provider assesses that the patient or SOFFA has learned the proper technique and can safely inject without supervision.

10. Order lab work for next visit:

- Liver enzymes
- Lipids
- Prolactin level
- Electrolytes, if taking spironolactone
- Complete blood count, if taking flutamide

11. Arrange follow up:

- Medical visit in 3 months
- Lab visit one week prior to medical visit
- Supportive counseling and education session in 1 month, if the need is identified
- Nursing visits for injection teaching as needed

Visit 7 - 9 months after initiating hormones	Medical Visit
Provider	Medical Provider
Goals of the Session	To continue health assessment after the initiation of hormone therapy To continue hormone therapy To continue the provision of primary care

1. **Take brief history with focus on:**
   - Patient's tolerance of hormones and anti-androgens
   - Any side effects patient may be experiencing
   - How transition is going
   - Cessation of erections/cessation of menses
2. **Perform brief physical exam.**
3. **Review lab results and discuss implications of abnormal findings.**
4. **Give vaccines as needed.**
5. **Discuss smoking cessation if appropriate.**
6. **Prescribe hormones, anti-androgens, syringes and needles for 6 months.**
7. **Order lab work for next visit:**
   - Complete blood count
   - Comprehensive metabolic panel (liver enzymes, electrolytes, lipid panel)
   - Prolactin (for MTF on estrogen)
8. **Arrange follow up:**
   - Medical visits every 6 months with lab visits one week prior and appointments for refills as needed.
   - Supportive counseling and education sessions and psychiatric consultations offered whenever the need is identified.
   - Continue routine, age-appropriate health care maintenance, including screening for sexually transmitted diseases if appropriate.

Special Considerations

1. **Hormone-Experienced Clients**
   - To minimize interruption in hormonal transition, clients who have who have been on hormones for more than 50% of the last two years can be prescribed hormones at the end of the first intake visit, after completing the informed consent forms and having baseline laboratory tests drawn.
   - Ongoing engagement in preventive health services should be strongly encouraged.

2. **Clients who have undergone gonadectomy (removal of the testes or ovaries)**
   - Transwomen/MTF: Lower doses of estrogens are recommended, usually half of the dose used before surgery, e.g. 1-2 mg estradiol daily. Anti-androgens (spironolactone) can be stopped, although clients may wish to continue dihydrotestosterone blockers if androgenic hair loss continues.
   - Transmen/FTM: Testosterone doses can be maintained at usual levels.
   - All clients: Monitor bone density, especially in clients with risk factors or who have stopped hormone therapy.

3. **Clients over 45 years/smokers**
   - Oral estrogens confer an increased risk of thromboembolic disease. Transdermal or parenteral routes are preferred over oral estrogen. Congugated estrogen (e.g., Premarin®) is not recommended.
   - Consider addition of aspirin

4. **HIV infection (see Appendix 3 - Managing Comorbidities)**
   - HIV disease is not a contraindication to hormone therapy.
   - Most antiretrovirals can be used safely although unboosted amprenavir (Agenerase®) or fosamprenavir (Lexiva®) are not recommended for coadministration with estrogens due to a decrease in amprenavir serum concentrations. See DHHS guidelines for updated information on drug-drug interactions.
   - Screen for osteoporosis in accordance with current prevention guidelines for HIV-infected individuals. Monitor vitamin D levels and replace if low.
   - Consider monitoring estradiol levels when initiating or changing anti-retroviral therapy.
   - Consider addition of aspirin.

5. **Screening Guidelines**

   Clients may avoid regular physical examinations and screening procedures due to fear of discrimination, encountering providers who are inadequately trained in transgender health, or personal discomfort with their physical bodies. There are no national screening guidelines transgender-specific for clients receiving hormones. Standard screening guidelines should be followed for the natal sex, with the following additions:

   - Clients who have undergone vaginoplasty (either penile inversion or colo-vaginoplasty) do not have a cervix, therefore a Papanicolaou test is not required. An annual examination should be done with the goal to detect problems such as granulation tissue, ulcers and other skin lesions.
   - Transmen/FTM who have undergone bilateral mastectomy may still have breast tissue remaining. Conduct an annual clinical chest exam. The decision for mammography according to natal guidelines should be discussed with the client.
   - Transwomen/MTF on estrogen, who have no known increased risk of breast cancer, should follow breast screening guidelines recommended for natal females.
   - The rates of osteoporosis may be increased in transwomen. Follow screening guidelines for natal females.

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APPENDIX 1 - CONSENT FORMS

1. For Women of Transgender Experience, Initiation of Care
2. For Men of Transgender Experience, Initiation of Care

Medical Record Number: _____

Consent Form 1

Date of Birth: _____

Patient Name: _____

SPECIFIC INFORMED CONSENT FOR HORMONE THERAPY FOR WOMEN OF TRANSGENDER EXPERIENCE

Initiation of Care

Hormone therapy is an important component of transition for some transgender clients, changing secondary sex characteristics to affirm a gender presentation that is consistent with their gender identity. While there are risks associated with taking feminizing/masculinizing medications, when appropriately prescribed they can greatly improve quality of life and psychological well-being. The goal of this consent form is to review the potential risks and benefits associated with use of hormone therapy.

A. The full medical effects and safety of hormone therapy are not fully known. Potential adverse effects may include, but are not limited to:
   - Increased or decreased cholesterol and/or fats in the blood, which may increase risk for heart attack or stroke
   - Increased levels of potassium in the blood, which may cause abnormal heart rhythms.
   - Increased risk of the following
     Blood clots, (deep venous thrombosis, pulmonary embolism);
   - Breast tumors/cancer
   - Heart disease, arrhythmias, and stroke;
   - High blood pressure
   - Liver inflammation
   - Pituitary tumors (tumor of small gland in the brain which makes prolactin)
   - Decreased number of red blood cells (anemia)
   - Acne
   - Increased or decreased sex drive and sexual functioning
   - Psychiatric symptoms such as depression and suicidal feelings; anxiety; psychosis (disorganization and loss of touch with reality), and worsening of pre-existing psychiatric illnesses.

B. Some side effects from hormones are irreversible and can cause death.

C. The risks for some of the above adverse events may be INCREASED by
   - Pre-existing medical conditions
   - Pre-existing psychiatric conditions
   - Cigarette smoking
   - Alcohol use

D. Irreversible body changes (potential increases with length of time on hormones) resulting from hormone therapy may include, but are not limited to:
   - Breast growth
   - Decreased bone density
   - Fat redistribution
   - Genital changes (i.e., smaller testes & penis)
   - Infertility

E. My signature below constitutes my acknowledgement of the following:

- My medical provider has discussed with me the nature and purpose of hormone therapy; the benefits and risks, including the risk that hormone therapy may not accomplish the desired objective; the possible or likely consequences of hormone therapy; and all feasible alternative diagnostic or treatment options
- I have read and understand the above information regarding the hormone therapy, and accept the risks involved
- I have met with a provider for education and support regarding hormone therapy
- I have received a list of community services and resources for people of transgender experience
- I have had sufficient opportunity to discuss my condition and treatment with the medical provider, nursing staff, and/or other staff, and all of my questions have been answered to my satisfaction
- I believe I have adequate knowledge on which to base an informed consent to the provision of hormone therapy
- I authorize and give my informed consent to the provision of hormone therapy

Signature of Client: **Date:**

Legal Name of Client (Printed):

Signature of Witness: **Date:**

Name of Witness (Printed):

Medical Provider's Name:

Medical Record Number: _____

Consent Form 1

Date of Birth: _____

Patient Name: _____

SPECIFIC INFORMED CONSENT FOR HORMONE THERAPY FOR MEN OF TRANSGENDER EXPERIENCE

Initiation of Care

Hormone therapy is an important component of transition for some transgender clients, changing secondary sex characteristics to affirm a gender presentation that is consistent with their gender identity. While there are risks associated with taking feminizing/masculinizing medications, when appropriately prescribed they can greatly improve quality of life and psychological well-being. The goal of this consent form is to review the potential risks and benefits associated with use of hormone therapy.

A. The full medical effects and safety of hormone therapy are not fully known. Potential adverse effects may include, but are not limited to:
    - Increased cholesterol and/or fats in the blood, which may increase risk for heart attack or stroke
    - Increased number of red blood cells (increased hemoglobin) which may cause headache, dizziness, heart attack, confusion, visual disturbances, or stroke
    - Acne

Increased risk of the following:
- Heart disease and stroke
- High blood pressure
- Liver inflammation
- Increased or decreased sex drive and sexual functioning
- Psychiatric symptoms such as depression and suicidal feelings; anxiety; psychosis (disorganization and loss of touch with reality), and worsening of pre-existing psychiatric illnesses

B. Some side effects from hormones are irreversible and can cause death.

C. The risks for some of the above adverse events may be INCREASED by
    - Pre-existing medical conditions
    - Pre-existing psychiatric conditions
    - Cigarette smoking
    - Alcohol use

D. Irreversible body changes (potential increases with length of time on hormones) resulting from hormone therapy may include, but are not limited to:
    - Deepening of voice
    - Development of facial & body hair
    - Fat redistribution
    - Genital changes (i.e. enlargement of clitoris & labia, vaginal dryness)
    - Increased bone density
    - Infertility
    - Male pattern baldness

E. My signature below constitutes my acknowledgement of the following:

- My medical provider has discussed with me the nature and purpose of hormone therapy; the benefits and risks, including the risk that hormone therapy may not accomplish the desired objective; the possible or likely consequences of hormone therapy; and all feasible alternative diagnostic or treatment options
- I have read and understand the above information regarding the hormone therapy, and accept the risks involved
- I have received education and support regarding hormone therapy
- I have received a list of community services and resources for people of transgender experience
- I have had sufficient opportunity to discuss my condition and treatment with the medical provider, nursing staff, and/or other staff, and all of my questions have been answered to my satisfaction
- I believe I have adequate knowledge on which to base an informed consent to the provision of hormone therapy
- I authorize and give my informed consent to the provision of hormone therapy

Signature of Client: **Date:**

Legal Name of Client (Printed):

Signature of Witness: **Date:**

Name of Witness (Printed):

Medical Provider's Name:

APPENDIX 2 - TRANSGENDER HEALTH RESOURCE GUIDE

- NYC-Metro Area Transgender and Gender Non-Conforming (TGNC) Community Resources

Callen-Lorde's resource guide to community organizations and social and supportive services in the NYC-Metro area for TGNC people:

http://callen-lorde.org/our-services/sexual-health-clinic/transgender-health-services/resourceguide/

APPENDIX 3 - MANAGING CO-MORBIDITIES

1. Active Psychosis

Active psychosis is defined here as loss of contact with reality and a decline in general functioning. If a patient presents with active psychosis that is not centered on their gender identity, the patient should be stabilized by psychotropic medications and/or psychotherapy before beginning hormone therapy. A mental health professional with experience in transgender care must confirm the patient's ability to consent to treatment at the time hormone therapy is initiated. The treatment plan can be determined by the patient's medical and mental health providers and the patient. When setting the plan of transgender care including for hormone therapy, medical and mental health providers should also consider the impact of the psychological distress associated with a delay of hormone treatment.

2. Cigarette Smoking

While patients who smoke can begin hormone therapy, it should be made clear that for both women and men of transgender experience, smoking while taking hormones may increase the risk of adverse events. For patients on feminizing hormones, cigarette smoking may increase the likelihood of thrombotic events. For patients on masculinizing hormones, it may increase the potential for coronary artery disease. At every visit, the provider should actively engage the patient in negotiation around smoking cessation. Aspirin therapy may be considered.

3. Coronary Artery Disease

Hormone therapy is not contraindicated in the presence of stable coronary artery disease. The provider should intervene to decrease all other risk factors for coronary artery disease. Transdermal estrogen therapy may be preferred over alternate routes of administration.

4. Dementia

Dementia is not an absolute contraindication to hormone therapy. Hormone therapy can be provided to patients who are able to give informed consent. For patients who cannot give consent, provision of hormone therapy should be decided on a case-by-case basis, e.g., involvement of guardian. Education of all caretakers is an important component of the treatment plan.

5. History of Deep Venous Thrombosis, Pulmonary Embolism or Embolic Stroke

Some forms of estrogen may increase future risk of venous thromboembolism (VTE). In one study only ethinyl estradiol was liked to VTE among transgender women. Use of transdermal estrogens may be preferred. Patients should be aware of the potential increased risk of complications as part of the informed consent process.

6. Homicidal/Suicidal Ideation/Attempts

Patients presenting with active suicidal or homicidal ideation or attempts should be engaged in mental health care. A mental health professional with experience in transgender care should be involved in the treatment plan. When setting the plan of transgender care including a time frame for hormone therapy. Medical and mental health providers should also consider the impact of the psychological distress associated with a delay of hormone treatment.

7. Liver Disease

If the patient has a self-limited hepatic infection, such as acute Hepatitis A or B, initiation of hormone therapy should be delayed until the patient is in the convalescent stage and transaminases have returned to normal. If the patient has chronic hepatitis for which treatment is available, such as Hepatitis C, treatment should be pursued. Patients with chronic hepatitis should be closely monitored during initiation of hormones or hormone dosage change. If transaminases (ALT) increases 2 times above baseline then consultation with hepatologist is advised.

Transdermal/parenteral hormones are preferred to oral administration. For all patients with chronic liver disease, the primary care provider should minimize the risk of further liver injury with appropriate immunizations and behavioral interventions.

8. Pituitary Adenoma

If the patient has a history of pituitary adenoma, estrogen therapy should be delayed until the patient has had a full evaluation and clearance from an endocrinologist.

9. Uncontrolled Diabetes

There is no clear evidence on the relationship between hormone therapy and glycemic control in diabetics. Diabetes should be managed independent of hormone therapy.

10. Uncontrolled Hypertension

Hypertension should be managed independently of hormone therapy. Spironolactone is the preferred anti-androgen.

11. Substance Use

Substance use is not a contraindication to hormone therapy. In some cases, hormone therapy may increase the likelihood of patients engaging in treatment for substance use. When making referrals it is important to ensure that the program will affirm the patient's gender identity.

12. HIV Infection

HIV disease is not a contraindication to hormone therapy. In fact, hormone therapy may improve engagement and retention in care.

There are no specific data on interactions between the doses of estrogens commonly used in feminizing regimens and antiretroviral regimens. Most of the available data is based on studies with oral contraceptives (ethinyl estradiol). Metabolism of estrogens occurs via the cytochrome P450 enzyme system, thus potential drug-drug interactions may exist between estrogens and Non-nucleoside reverse transcriptase inhibitors (NNRTIs) and the Protease inhibitors (PIs). Most boosted PIs decrease ethinyl estradiol levels. The effects of Non-nucleosides vary, e.g. nevirapine decreases estrogen levels, etravirine and rilpvirine increase ethinyl estradiol levels, whereas efavirenz appears to have no effect affect levels. There are no known drug-drug interactions between ethinyl estradiol and NRTIs / NtRTIs / integrase inhibtors / CCR5 antagonists/fusion inhibitors. DHHS recommends that oral contraceptives and amprenavir (or fosamprenavir) not be co-administered due to decrease in amprenavir serum concentrations; therefore, we recommend avoiding the use of amprenavir (Agenerase) and fosamprenavir (Lexiva) with estrogens.

Consider monitoring estradiol levels when initiating or changing anti-retroviral therapy.

APPENDIX 4 - MANAGING LABORATORY ABNORMALITIES

1. Anemia

If a patient develops hemoglobin less than 11gm/dL and the patient is taking flutamide, the flutamide should be discontinued and the hemoglobin should be rechecked one month later. If it remains abnormal, a full anemia work-up should be initiated.

2. Erythrocytosis

Testosterone may result in an elevated hematocrit due to increased erythropoiesis. It is important to rule out other causes of erythrocytosis such as polycythemia vera. Hematocrit should be maintained at less than 45%. If the hematocrit increases above 52%, measures include initiation of phlebotomy, decreasing the dose of intramuscular testosterone, or switching to transdermal testosterone gel.

3. Elevated Prolactin Level

If a patient has a prolactin level between 20 and 100 ng/mL, the patient should be followed with history (focusing on visual field deficits, headaches) and physical exam (blood pressure, fundoscopic exam and gross visual field assessment). For prolactin levels 40-100 ng/mL, reduce estrogen levels by half and recheck in 6-8 weeks. Continue hormones at the lower dose if prolactin levels remain under 40ng/mL. If a patient has a prolactin level over 100ng/mL, hormones should be discontinued, and the level should be rechecked. If it remains over 100ng/mL, an MRI of the pituitary should be obtained to rule out pituitary adenoma. If the MRI is normal, hormones can be restarted at a lower dose, and prolactin level should be followed. If it continues to rise, or if the MRI is abnormal, the patient should be referred to an endocrinologist.

Guidelines for Elevated Prolactin Level

LEVEL (ng/mL)	ACTION
< 25	Continue to monitor per protocol.
25-40	Ask patient about outside sources of estrogen and continue to monitor per protocol.
40-100	Decrease estrogen does by half and recheck in 6-8 weeks
>100	Stop estrogen and recheck in 6-8 weeks. If level remains high, MRI pituitary. If level decreases, restart estrogen at lower dose.

Adapted from Whitman Walker Transgender Protocols 2010

4. Elevated Transaminases (LFTs)

Elevated Transaminases should be defined as AST/ALT greater than three times the upper limit of normal or twice baseline if the patient has chronically elevated liver enzymes. If transaminases are elevated, hormone therapy should be discontinued while a work up is initiated. The initial evaluation should include a careful history of the patient's symptoms and use of alcohol, hormones that were not prescribed by the provider, other prescription, over the counter and herbal medications, and other potential hepatotoxic agents* as well as evaluation for acute and chronic hepatitis. If acute viral hepatitis is diagnosed, hormone therapy should be withheld until the patient is in the convalescent stage and transaminases have returned to normal. If no identifiable cause is revealed, transaminases should be rechecked two months after stopping hormone therapy. If they have returned to normal, the provider can conclude that the hormones were causing the liver inflammation, and they can be restarted and maintained at a lower dose, or a different medication can be tried. If transaminases remain abnormal, the patient should be referred for evaluation by a gastroenterologist.

* Medications to consider include acetaminophen, phenytoin, valproic acid, sulfonamides, nitrofurantoin, isoniazid, rifampin, niacin and alpha-methyldopa.

APPENDIX 5

TABLES OF MEDICATIONS AND THEIR EFFECTS

Table 1: Feminizing Regimens

MEDICATION & STRENGTH	INITIAL DOSE	MAXIMUM DOSE	INTENDED EFFECTS	POSSIBLE SIDE EFFECTS	LABS TO MONITOR
Estradiol Cypionate 5mg/ml (Depo-Estradiol®)	2.5mg (0.5cc) Intramuscularly Every two weeks	5mg (1cc) Intramuscularly Every two weeks	Hypertrophy of breasts Impotence Redistribution of fat Testicular atrophy Reversal of androgenic hair loss Loss of body hair Softening of skin	Cerebrovascular Accident (Stroke) Deep Vein Thrombosis Pulmonary Embolism Depression Gallbladder disease Gastrointestinal upset Headache Hepatitis Hypercalcemia Hyperlipidemia Hypertension Impotence Loss of libido Mood changes Pituitary adenoma Sterilization	Lipids Liver enzymes Prolactin
Estradiol Valerate 20mg/ml or 40mg/ml (Delestrogen®)	10-20mg Intramuscularly Every two weeks	20-40mg Intramuscularly Every two weeks			
Estradiol (Estrace®)	1 mg Orally, twice daily	4 mg Orally, twice daily			
Estradiol transdermal Patch 0.1mg (Vivelle-Dot®)	1 patch Topically, twice weekly	2 patches Topically, twice weekly			
Conjugated estrogens 1.25mg/2.5mg (Premarin®)	1.25 mg Orally, twice daily	2.5mg Orally, twice daily			
Medroxyprogesterone acetate, e.g. Provera®	5mg orally, once daily	10mg orally once daily	Hypertrophy of breasts (disputed)	Weight gain, dyslipidemia, depression, dizziness In combination with estrogen: DVT: pulmonary embolism, stroke, myocardial infarction, Invasive breast cancer (in cisgender women)	Lipids, CBC, LFTs
Depot medroxyprogesterone acetate, e.g. DepoProvera®	150 mg Intramuscularly, every 3 months	150 mg Intramuscularly , every 3 months			
Micronized progesterone (Prometrium®)	100mg orally, Once daily	200 mg orally, Once daily			

Notes for Table 2, Anti-Androgens:

Choosing an Anti-Androgen

Spironolactone should be the first line Anti-Androgen as it is both safe and cost effective. It should be avoided only in patients who have a history of hyperkalemia, low blood pressure, or renal failure. In the presence of these, Flutamide can be used. Finasteride and dutasteride are weaker anti-androgens (dihydrotestosterone blockers) that may be used alone if other anti-androgens are contraindicated or not tolerated. They can also be used in conjunction with the anti-androgens if the patient is experiencing androgenic alopecia.

Note: Anti-Androgens are not needed in transgender women who have undergone orchiectomy.

Table 2: Anti-Androgens

MEDICATION & STRENGTH	INITIAL DOSE	MAXIMUM DOSE	INTENDED EFFECTS	POSSIBLE SIDE EFFECTS	LABS TO MONITOR
Spironolactone (Aldactone®) 25mg, 50mg, 100mg	75-100 mg Orally in divided daily dosing	200-400mg Orally in divided daily dosing	Decrease of androgenic alopecia Impotence Thinning and decrease of body and facial hair Hypertrophy of breasts	Ataxia Gastric ulcer Gastronintestinal upset Headache Hirsutism Hyperkalemia Hyponatremia Hypotension Mood Changes	Electrolytes
Flutamide (Eulexin®) 125mg	125 mg Orally, twice daily	125 mg Orally, twice daily		Anemia Gastrointestinal upset Hot flashes Impotence Loss of libido Mood Changes Rash Testosterone elevation*	Complete Blood count Liver enzymes
Finasteride (Proscar®) 5mg (Propecia®) 1mg	1mg Orally, once daily	5mg Orally, once daily	Decrease of androgenic alopecia	Decreased libido Impotence Mood Changes Testosterone elevation*	Liver enzymes
Dutasteride (Avodart) 0.5mg	0.5mg Orally, once daily	0.5mg Orally, once daily			
Cyproterone acetate (Androcur®)	50mg	150mg	Decrease of androgenic alopecia Impotence Thinning and decrease of body and facial hair Hypertrophy of breasts	Thromboembolic events Hepatic toxicity Benign and malignant liver tumors Intraabdominal hemorrhage Meningioma Anemia Depression	Complete Blood count Liver enzymes Electrolytes

* Dutasteride, finasteride and flutamide may cause a transient elevation in testosterone that is probably not clinically significant

Table 3: Masculinizing Regimens

MEDICATION & STRENGTH	INITIAL DOSE	MAXIMUM DOSE	INTENDED EFFECTS	POSSIBLE SIDE EFFECTS	LABS TO DRAW
Testosterone Cypionate 100mg/ml Or 200mg/ml	100 mg Intramuscularly, every two weeks --- Same dose for post-oophorectomy men	200 mg Intramuscularly, every two weeks --- 100 mg Intramuscularly, every two weeks for post-oophorectomy men	Clitoral hypertrophy Growth of facial and body hair Increase in muscle mass and definition Increase of androgenic alopecia Lowering of vocal pitch	Acne Amenorrhea Androgenic alopecia Depression Gastrointestinal upset Headache Hepatitis Hyperlipidemia Hypertension Mood Changes Polycythemia	Complete Blood Count Lipids Liver enzymes Prolactin
Testosterone Enanthate* 100mg/ml Or 200mg/ml	100 mg Intramuscularly, every two weeks --- Same dose for post-oophorectomy men	200 mg Intramuscularly, every two weeks --- 100 mg Intramuscularly, every two weeks for post-oophorectomy men			
Testosterone gel (Testim® or Androgel®) 1mg/g (1%)	2.5mg Topically daily	5-10 mg Topically daily			
Testosterone patch (Androderm®) 2.5mg or 5mg	2.5mg Patch daily	5mg Patch daily		As above Local irritation	

* Testosterone Enanthate is supplied only in 5cc vials. Therefore, it is not listed as an option in the parts of the protocol that require prescribing less than 5cc. If a patient is hormone experienced and already taking Testosterone Enanthate, this can be substituted for Testosterone Cypionate.

Table 4A: Masculinizing Effects in FTM Clients Receiving Testosterone

EFFECT	ONSET (MONTHS)	MAXIMUM (YEARS)
Skin oiliness/acne	1-6	1-2
Facial hair	6-12	4-5
Androgenic hair loss (scalp)	6-12	
Increased muscle mass	6-12	2-5
Fat redistribution	1-6	2-5
Cessation of menses	2-6	
Clitoral enlargement	3-6	1-2
Vaginal atrophy	3-6	1-2
Deepening of voice	6-12	1-2

Table 4B: Feminizing Effects in MTF Clients Receiving Estrogen and Anti-Androgen

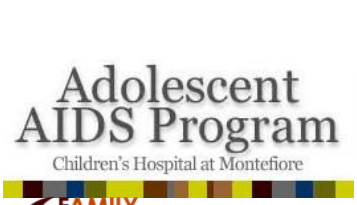
EFFECT	ONSET (MONTHS)	MAXIMUM (YEARS)
Decrease in muscle mass and strength	3-6	1-2
Softening of skin	3-6	unknown
Decreased erections	1-3	3-6
Breast growth	3-6	2-3
Decreased testicular volume	3-6	2-3
Decreased sperm production	Unknown	>3
Voice changes	none	

Adapted from The Endocrine Society Clinical Practice Guidelines, 2009

CALLEN LORDE
COMMUNITY HEALTH CENTER

TRANSGENDER HEALTH SERVICES

We would like to thank our colleagues for their support, assistance and expertise:



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