

FTM Clinical Approach and Protocols

Gender Health Center, Hormone Clinic
Sacramento, CA
Katherine Gardner, MD, Medical Director
Revised 11/6/2015

Name and Pronouns:

Preferred names and pronouns are used at all times when referring to the patient, both when the patient is present and when discussing patients outside the presence of the patient. Because preferred names and pronouns can change, it is important that if, at anytime, the preferred name and pronoun are not known, that the patient is asked. For rare instances when the preferred name and pronoun cannot be used (for example, on prescriptions when the current legal name must be used), the patient is notified that this is happening and why it is happening.

Informed Consent Model of Prescribing:

Hormones are prescribed based on an informed consent model. The informed consent model requires: 1) thorough medical, surgical, social, psychiatric, and gender history 2) that the provider has an understanding of what the patient wants from hormones, allowing appropriate counseling regarding expectations 3) extensive counseling regarding the effects of testosterone, long-term, short-term, permanent 4) discussion of risks of testosterone 5) discussion regarding impact on fertility 6) no medical contraindications 7) capacity to provide medical consent or the consent of those who make medical decisions for the patient. Counseling and therapy is NOT required however, as it is for any patient, if appropriate, based on mood symptoms identified during the appointment, it is strongly recommended.

General Guiding Principles of Prescribing Hormones for Medical Transition:

The goal of therapy is to achieve effects identified by the patient as important to them. Because of this, the focus of all appointments is talking with the patient about their expectations/concerns and counseling about the expected effects and timelines.

Testosterone is dosed based on desired effect to a safe upper limit. Means that some patients will be on different doses. For example, some patients do not want the full masculinizing effects of testosterone and may prefer to be on a lower dose while others will want a full dose with expectations to achieve all masculinizing effects that testosterone causes.

Because of the above, serum testosterone levels are not used to determine dosing or titration and testosterone levels are not checked routinely. Titration of the testosterone dose is to clinical and desired effect. Testosterone levels may be checked if there are problems. For example, vaginal bleeding, lack of desired effect, etc. In these cases, trough testosterone levels outside the "normal male" range (either too high or too low) may be the underlying cause.

Common question regarding testosterone/mood instability: testosterone at these levels has not

been shown to cause anger/outbursts/"roid rage."

Testosterone:

Important to note that there are NO medications/hormones that currently have FDA approval for the indication of medical gender transition.

1) Testosterone Cypionate 200mg/cc, 10 mL vial (also comes in 1mL, 20mL vials)

Subcutaneous injection of testosterone is currently the most popular method of delivery of testosterone in the trans community. Safe self injection into the subcutaneous tissue of the abdomen needs to be taught to patients. Testosterone is administered subcutaneously in the abdomen once a week.

This is our clinic's preferred method of administration of testosterone because:

- Smaller needles, less needle phobia, easier for patients to self inject
- Less testosterone is needed to achieve the same effects as intramuscular injection (see below)
- Less scar tissue builds up over time

It is important to note that subcutaneous injection must be done every 7 days,

Intramuscular injection q14 days however some prefer to cut the dose in half and do half that dose q7 days. Safe self injection into the quadricep muscle needs to be taught to patients.

How to counsel regarding dosing schedule:

- Pros for injecting every 7 days: Idea is that the patient avoids high peaks and low troughs of testosterone. Anecdotally, patients report more stable mood with dosing every 7 days. However, there is no evidence to support this idea and dosing every 14 has been the standard. Injecting more frequently than every 7 days is not recommended
- Cons for injecting every 7 days: In theory, the patient will be on IM testosterone for life. Scar tissue develops making injections more difficult and absorption more variable after years of injections. If injections can be kept to a minimum, the scar tissue burden is less.

2) Testosterone gel: Not used in our clinic because absorption is variable and dosing consistently is difficult. Also, the titration schedule is not as clearly defined. For transmen using testosterone cream, do need to consider that they may unintentionally expose an intimate partner to testosterone cream.

3) Testosterone patches: none currently exist

4) Testosterone pellets: come on and off the market.

Not prescribed in our clinic because:

- Small procedure is required to place them
- Have not been shown to deliver consistent levels of testosterone so far

Other Considerations:

Testosterone and needles are covered by most insurance companies in California (including medical and medicare)

- To fill out prior authorization or TAR, diagnosis is Endocrine Society NOS ICD-9 code: 295.9; Medical Necessity: Testosterone is the only approved medical treatment for FTM gender identity disorder

For cash pay patients:

- 10 mL vial through Strohecker's compounding pharmacy in Oregon is about \$50
<http://www.stroheckersrx.com/>

- 10mL vial at Costco is \$65, however they do not sell needles
- 10mL vial at CVS, Walgreens can be \$100 + without insurance

Prescription Protocols:

FTM Clinical Approach and Protocol (>18 yo)

Criteria

- Age >18
- Has capacity to provide consent
- No breast/uterine cancer, erythrocytosis (hematocrit >50%), severe liver dysfunction (transaminases >3x upper limit of normal)
- Tobacco use should be discouraged but does not change dosing

Subcutaneous Testosterone Dosing

Rx	Initial/Low Dose	Standard Dose	High Dose
Testosterone Cypionate 200mg/cc 10mL vial	40mg q 7 days 0.2cc q 7 days	60-80mg q7 days 0.3-0.4 cc q7 days	100mg q7 days 0.5cc q7 days
Syringe**	1cc syringe #15	1cc syringe #15	1cc syringe #15
25 gauge 5/8 inch needle to be used for drawing and injecting	#15	#15	#15

** Does not require rx but is helpful to note for pharmacy

Titration q3 months by 20mg/0.1cc

Intramuscular Testosterone Dosing

Rx	Initial	Standard	High
Testosterone Cypionate 200mg/cc 10mL vial	100mg q 14 days 0.5cc q 14 days*	150-200mg q14 days 0.75-1 cc q14 days*	250mg q14 days 1.5cc q14 days*
Syringe**	1cc syringe #15	1cc syringe #15	3cc syringe #15
18 gauge 1.5 inch needle to be used for drawing	#15	#15	#15
22 gauge 1 inch needle to be used for injecting	#15	#15	#15

* Dose can be cut by 50% for injecting q7 days

** Does not require rx but is helpful to note for pharmacy

Titration q3 months by 50-100mg

FTM Clinical Approach and Protocol (16-17 yo)

Criteria

- Age 16-17
- Able to understand discussed effects/permanent changes/risks, guardian consent also required
- Connected to regular counseling, peer group meetings etc strongly recommended
- No breast/uterine cancer, erythrocytosis (hematocrit >50%), severe liver dysfunction (transaminases >3x upper limit of normal)
- Tobacco use should be discouraged but does not change dosing

Subcutaneous Testosterone Dosing

Rx	Initial/Low Dose	Standard Dose	High Dose
Testosterone Cypionate 200mg/cc 10mL vial	20mg q 7 days 0.1cc q 7 days	20-40mg q7 days 0.1-0.2 cc q7 days	60mg q7 days 0.3cc q7 days
Syringe**	1cc syringe #15	1cc syringe #15	1cc syringe #15
25 gauge 5/8 inch needle to be used for drawing and injecting	#15	#15	#15

** Does not require rx but is helpful to note for pharmacy

Titration q3-6 months by 20mg/0.1cc

Intramuscular Testosterone Dosing

Rx	Initial/Low Dose	Standard	High
Testosterone Cypionate 200mg/cc 10mL vial	50mg q 14 days 0.25cc q 14 days*	100-200mg q14 days 0.5-1 cc q14 days*	200mg q14 days 1cc q14 days*
Syringe**	1cc syringe #15	1cc syringe #15	1cc syringe #15
18 gauge 1.5 inch needle to be used for drawing	#15	#15	#15
22 gauge 1 inch needle to be used for injecting	#15	#15	#15

* Dose can be cut by 50% for injecting q7 days

** Does not require rx but is helpful to note for pharmacy

FTM Clinical Approach and Protocol (<16 yo)

Based on

- 1) UCSF Center of Excellence for Transgender Health
<http://transhealth.ucsf.edu/trans?page=protocol-youth>
- 2) Expert opinion through Transgender Medical Consultation Service
- 3) *Endocrine Treatment of Transsexual Persons: an Endocrine Society Clinical Practice Guideline*, September 2009

Criteria:

- Tanner Stage II or greater
- Participation in counseling. Can be individual, group or family

Currently, our clinic is not prescribing hormones to patients under the age of 16. This is not because patients under 16 cannot be prescribed hormones but because the structure of our clinic does not provide an environment in which it is responsible to prescribe to patients under 16. Patients under 16 will require multiple frequent visits with their families and likely more extensive counseling/exploration of when it would be an appropriate time to start hormones leading up to the decision to initiate hormone therapy. Currently, our clinic operates 2 Friday nights a month without a way for families or patients to contact us outside of these clinic hours. As our clinic changes, our hope is to be able to accommodate younger patients. Patients under age 16, can and are safely prescribed hormones by providers in other settings (for example a clinic that has weekday hours and who has medical coverage throughout the week).

“Puberty Blockers:”

Idea is that after reaching Tanner Stage II (which can happen between ages (8-12), puberty should be held off until the patient is mature enough to fully understand the effects/permanent changes/risks of testosterone. The reasoning behind this thought is not backed by the data that currently exists on trans youth. From all data, it seems that once a child enters puberty, gender identity is consistent with their future gender identity of adulthood. Studies have found that all adolescents who identify with a gender other than their assigned gender at birth have this identity persist into adulthood. This is not the case for children prior to puberty who identify as a gender other than their assigned gender at birth.

GnRH, leuprolide 7.5mg IM monthly, comes in 7.5mg vials
Depo Provera q 12 weeks

Considerations:

- 1) Cost: GnRH is very expensive, several hundred dollars for a vial which is only a month - HOWEVER recently, this has been covered by most California insurance companies
- 2) Effect, while patients won't experience masculinizing effects with leuprolide, benefit is that breasts won't grow (binding of breasts will be easier and top surgery will be easier) and menses will cease.
- 3) Depo Provera will stop menses but will not stop breast growth

Labs Protocol (all ages):

Initial Visit:	Every 3 months until on a stable dose	Every 6-12 months once on a stable dose	3 months after any dose change
CBC, CMP, lipid panel (if >30)	CBC, CMP, lipid panel (if >30)	CBC, CMP, lipid panel (if >30)	CBC, CMP, lipid panel (if >30)

Follow Up Protocol (all ages):

Every 3 months until on a stable dose, every 6-12 months once on a stable dose. Make sure to bring in the patient for follow up 3 months after any dose change.

Health Maintenance and Screening:

- Cervical Cancer Screening: starting at age 21, every 3 (or 5 if doing HPV testing with pap) years while patient has a cervix
- Breast Cancer Screening: Mammography for patients with breasts based on current screening guidelines. For patients who have had mastectomy, examination of chest and axilla
- STI Screening as appropriate (assess with every visit)
- Assess for need PrEP based on risk
- Colon Cancer Screening starting at age

Expectations (based on being on standard dose of testosterone):

From Endocrine Treatment of Transsexual Persons: an Endocrine Society Clinical Practice Guideline, September 2009

Effect	Onset (months)	Maximum (years)
Skin oiliness/acne	1-6	1-2
Facial/body hair growth	6-12	4-5
Male pattern baldness	6-12	Continuous
Increased muscle mass/strength	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

REFERENCES:

1) World Professional Association for Transgender Health. Standards of Care (SOC) for the Health of Transsexual, Transgender, and Gender Nonconforming People, 7th version:
http://www.wpath.org/publications_standards.cfm

2) Center of Excellence for Transgender Health, UCSF. Primary Care Protocol for Transgender Patient Care: <http://transhealth.ucsf.edu/trans?page=protocol-00-00>

3) Clinical Protocol Guidelines for Transgender Care. Vancouver Coastal Health:
<http://transhealth.vch.ca/resources/careguidelines.html>

4) Endocrine Society's Clinical Guidelines: *Endocrine Treatment of Transsexual Persons: an Endocrine Society Clinical Practice Guideline, September 2009*
www.endosociety.org/guidelines/final/upload/endocrine-treatment-oftranssexual-persons.pdf

5) UCSF Center of Excellence for Transgender Health
<http://transhealth.ucsf.edu/trans?page=protocol-youth>

6) Lyon-Martin Clinical Guidelines
<http://lyon-martin.org/services/transgender/>

7) Gender Health Center, Sacramento (916) 455-2391
<http://www.thegenderhealthcenter.org/>

8) Trans Line
<http://project-health.org/transline/>

9) Transgender Law and Policy Institute
<http://transgenderlaw.org/>

With any questions:

Katherine Gardner, MD

Email: katherinegardner@gmail.com

Gender Health Center
2020 29th St #201 Sacramento, CA 95817
(916) 455-2391