Bone health and osteoporosis (/guidelines/bone-health-and-osteoporosis)

HIV (/guidelines/hiv)

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Overview of masculinizing hormone therapy

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Introduction

The goal of masculinizing hormone therapy is the development of male secondary sex characteristics, and suppression/minimization of female secondary sex characteristics. General effects include the development of facial hair, virilizing changes in voice, a redistribution of facial and body subcutaneous fat, increased muscle mass, increased body hair, change in sweat and odor patterns, frontal and temporal hairline recession, and possibly male pattern baldness. Sexual and gonadal effects include an increase in libido, clitoral growth, vaginal dryness, and cessation of menses. An ovulatory state is common, though not absolute and long-term fertility may be affected, though some transgender men are able to discontinue testosterone and achieve successful pregnancy.[1] Masculinizing hormone therapy may bring about changes in emotional and social functioning, though these can vary from person to person and stereotypes should be avoided. The general approach involves the use of one of

several forms of parenteral testosterone.

All testosterone preparations currently used in the U.S. are "bioidentical", meaning they are chemically equivalent to the testosterone secreted from the human testicle. Prior use of oral methyltestosterone and other synthetics commonly encountered in bodybuilding communities has resulted in unsubstantiated concerns about negative hepatic effects of testosterone use in transgender men. Testosterone is available in a number of injected and topical preparations, which have been designed for use in non-transgender men with low androgen levels (see table). Since the label dosing (not included in table) for these medications are based on the treatment of men with low, but not no, testosterone, higher dosing may be needed in transgender men (see table) than are commonly used in non-transgender men.

Table 1. Hormone preparations and dosing (Grading: T O M)

Androgen	Initial - low dose[b]	Initial - typical	Maximum - typical[c]	Comment
Testosterone Cypionate[a]	20 mg/ week IM/ SQ	50mg/week IM/ SQ	100mg/week IM/SQ	For q 2 wk dosing, double each dose
Testosterone Enthanate[a]	20mg/ week IM/ SQ	50mg/week IM/ SQ	100mg/week IM/SQ	"
Testosterone topical gel 1%	12.5-25 mg Q AM	50mg Q AM	100mg Q AM	May come in pump or packet form
Testosterone topical gel 1.62%[d]	20.25mg Q AM	40.5 - 60.75mg Q AM	103.25mg Q AM	"
Testosterone axillary gel 2%	30mg Q AM	60mg Q AM	90-120mg Q AM	Comes in pump only, one pump = 30mg

Androgen	Initial - low dose[b]	Initial - typical	Maximum - typical[c]	Comment
Testosterone Undecanoate[f]	N/A	750mg IM, repeat in 4 weeks, then q 10 weeks ongoing	N/A	Requires participation in manufacturer monitored program[f]

a. Available as standard U.S. Pharmacopeia (USP) as well as compounded products.

b. Initial - low dose recommended for genderqueer and nonbinary dosing.

c. Maximum dosing does not mean maximal effect. Furthermore, these dosage ranges do not necessarily represent a target or ideal dose. Dose increases should be based on patient response and/or monitored hormone levels. Some patients may require less than this amount, and some may require more.

d. Doses of less than 20.25mg with 1.62% gel, or less than 30mg with 2% axillary gel may be difficult, since measuring one-half of a pump or packet can present a challenge. Patients requiring doses lower than 20.25mg and whose insurance does not cover 1% gel may require prior authorization or an appeal.

e. Testosterone creams are prepared by individual compounding pharmacies. Specific absorption and activity varies and consultation with the individual compounding pharmacist is recommended.

f. Testosterone undecanoate has been used extensively for transgender care outside of the U.S. for many years.[2,3] It has recently become available in the U.S. Testosterone undecanoate has been associated with rare cases of pulmonary oil microembolism and anaphylaxis. As such in the United States, the drug is available only through a restricted program called the AVEED Risk Evaluation and Mitigation Strategy (REMS) Program (http://www.aveedrems.com/AveedUI/rems/preHome.action). All injections must be administered in an office or hospital setting by a trained and registered health care provider and monitored for 30 minutes afterwards for adverse reactions.

Route of injection (intramuscular vs. subcutaneous): While testosterone for injection is labeled for the intramuscular route, many providers have administered testosterone using the subcutaneous route with good efficacy and patient satisfaction, and without complications.

Benefits of subcutaneous administration include a smaller and less painful needle, and may avoid scarring or fibrosis from long term (possibly > 50 years) intramuscular therapy (Grading: T O M).[4,5]

Proper use of transdermal testosterone gel: These gels involve an evaporable vehicle which contains the testosterone medication. Manufacturer labeling recommends applying in the morning. After application, the testosterone moves into the dermis, where it slowly releases over the course of the day. Care should be taken to avoid any contact of the gel with others, especially women and children. This includes gel, which remains on clothing or other fomites. Gel should be applied only to upper arms or shoulders, and not to other sites. Site of application should remain dry for at least 2 hours. It is also recommended that the application site be washed at a later time if close skin-skin contact with another person is expected.

Table 2. Titration and monitoring of masculinizing hormone therapy

Therapy	Comments	Baseline	3 months*	6 months*	12 months*	Yearly
Lipids	No evidence to support lipid monitoring at any time; use clinician discretion	Based on USPSTF guidelines				

* In first year of therapy only;
** is optional and may be helpful in complex cases (see text) Used to calculate bioavailable testosterone; monitoring bioavailable testosterone (http://www.issam.ch/freetesto.htm)

Therapy	Comments	Baseline	3 months*	6 months*	12 months*	Yearly
A1c or fasting glucose	No evidence to support lipid monitoring at any time; use clinician discretion	Based on USPSTF guidelines				
Estradiol						
Total Testosterone			X	X	X	
Sex Hormone Binding Globulin (SHBG)**			PRN			
Albumin**			PRN			
Hemoglobin & Hematocrit		X	X	X	X	X

* In first year of therapy only;
** is optional and may be helpful in complex cases (see text) Used to calculate bioavailable testosterone; monitoring bioavailable testosterone (http://www.issam.ch/freetesto.htm)

Titration upwards of dose should be driven by patient goals, in the context of clinical response, hormone level monitoring, and safety monitoring (i.e. hemoglobin and hematocrit [H&H]). Clinical response can be measured objectively by the presence of amenorrhea by 6 months.[4] Once within the normal male physiologic range, there is no evidence that higher doses/levels of testosterone result in a greater degree of virilization. Lab reference ranges for total testosterone levels are generally very wide (roughly 350-1100ng/dl); if men have testosterone levels at the lower end of the normal male range and are

either concerned about slow progress or are having symptoms of low energy, libido, or mood, it is reasonable to slowly increase the dose while monitoring for side effects. Once total testosterone is greater than the midpoint value in the lab reported reference range, it is unclear if an increase in dose will have any positive effect on perceived slow progress, or on mood symptoms or other side effects (/guidelines/feminizing-hormone-therapy#S7X). (http://transhealth.ucsf.edu/trans?page=guidelines-feminizing-therapy#S7X)

While some providers choose to omit hormone level monitoring, and only monitor for clinical progress or changes, this approach runs the risk of a suboptimal degree of virilization if testosterone levels have not reached the target range. A prospective study of 31 transgender men newly started on either subcutaneous 50-60mg/week testosterone cypionate, 5g/day 1% testosterone gel, or 4mg/day testosterone patch found that after 6 months only 21 (68%) achieved male range testosterone levels and 5 (16%) had persistent menses, with only 9 (29%) achieving physiologic male-range estradiol levels.[5] Some genderqueer and gender-nonconforming/nonbinary patients may prefer to maintain testosterone levels in an intermediate range. Regardless of initial dosing scheme chosen, titrate upwards based on testosterone levels measured at 3 and 6 months. Once hormone levels have reached the target range for a specific patient, it is reasonable to monitor levels yearly. As with testosterone replacement in non-transgender men, annual visits and lab monitoring are sufficient for transgender men on a stable hormone regimen. Endocrine Society guidelines recommend monitoring of hormone levels every 3 months.[6] In practice this is not realistic and not likely to add value once a stable dosing has been achieved.[7] Other reasons for measuring hormone levels in the maintenance phase include significant metabolic shifts such as the onset of diabetes or a thyroid disorder, substantial weight changes, subjective or objective evidence of regression of virilization, or new symptoms potentially precipitated or exacerbated by hormone imbalances such as hot flashes, pelvic cramping or bleeding, or migraines. Such patients may also require more frequent office visits to manage coexisting conditions. Increased frequency of office visits may also be useful for patients with complex psychosocial situations to allow for the provision of ancillary or wraparound services.

General comments on hormone level interpretation

Interpretation of laboratory results requires special attention in the context of transgender care. Numerous sources publish target ranges for serum estradiol, total estrogens, free, total and bioidentical testosterone, and sex hormone binding globulin. However, these specific ranges may vary between different laboratories and techniques. Furthermore, the interpretation of reference ranges supplied with lab result reports may not be applicable if the patient is registered under a gender that differs from their intended hormonal sex. For example, a transgender man who is still registered as female will result in lab reference ranges reported for a female; clearly these ranges are not applicable for a transgender man using virilizing hormone therapy. Hormone levels for genderqueer or gender nonconforming/nonbinary patients may intentionally lie in the mid-range between male and female norms. Providers are

encouraged to consult with their local lab to obtain hormone level reference ranges for both "male" and "female" norms, and then apply the correct range when interpreting results based on the current hormonal sex, rather than the sex of registration. Testosterone levels must also be interpreted in the context of knowing whether the specimen was drawn at the peak, trough or mid-cycle of the dosing interval, as values can vary widely (and if so may cause symptoms, see below and pelvic pain and bleeding guidelines (/guidelines/pain-transmen)).

Monitoring testosterone levels

Testosterone levels can be difficult to measure in non-transgender men due to rapid fluctuations in levels, relating to pulsatile release of gonadotropins. In transgender men who are receiving exogenous testosterone, levels may lack these rapid fluctuations (though they may vary over the dosing interval). Free testosterone represents the portion of testosterone unbound to serum proteins and depends on levels of sex hormone binding globulin (SHBG). Free testosterone can be measured, however assays are unreliable.[8] Consensus is lacking on the role of free vs. total testosterone levels; total testosterone levels are reliable and readily available, however they do not describe the actual bioavailable testosterone level. Bioavailable testosterone is free testosterone plus testosterone weakly bound to albumin.[9] SHBG is elevated in the presence of estrogen and thyroxine.[10] It is decreased in the presence of androgens, prolactin, and high levels of insulin and growth hormone. For transgender care, The Endocrine Society recommends monitoring of the total testosterone level.[11] Calculation of the bioavailable testosterone (http://www.issam.ch/freetesto.htm) is also likely to help guide dosing in complicated cases, or in cases where results or side effects exist in the setting of a normal range total testosterone. Bioavailable testosterone can be calculated from the total testosterone, albumin, and SHBG levels. A general reference range for bioavailable testosterone is > 72ng/dl (2.5nmol/L).[12-15]

Monitoring hormone levels in patients using injected testosterone

When measuring hormone levels in patients using injected forms of testosterone, a mid-cycle level is often sufficient however if the patient is experiencing cyclic symptoms such as migraines, pelvic cramping, or mood swings. Peak (1-2 days post injection) and trough levels of testosterone may reveal wide fluctuations in hormone levels over the dosing cycle; in these cases, consider changing to a transdermal preparation, or reducing the injection interval (with concomitant reduction in dose, to maintain the same total dose administered over time).[16,17]

Monitoring estradiol levels

A six-month prospective study of 31 transgender men newly started on testosterone found that only 9 (29%) achieved physiologic male-range estradiol levels.[18] In reality, physiologic female estradiol

ranges are wide and vary over the menstrual cycle; there can be significant overlap with the physiologic male range. Estradiol may play a role in pelvic pain or symptoms, persistent menses, or mood symptoms. It is unclear what role estrogen blockade with aromatase inhibitors (AI) or selective estrogen receptor modulators (SERM) might play in managing these symptoms, or in routine virilizing regimens. An in-depth discussion of pelvic pain and persistent menses (/guidelines/pain-transmen) is covered elsewhere in these guidelines.

Interpreting sex-specific, non-hormone labs

Alkaline phosphatase, hemoglobin and hematocrit, and creatinine may vary depending on the patient's current sex hormone configuration. Several factors contribute to these differences, bone mass, muscle mass, number of myocytes, presence or lack of menstruation, and erythropoietic effect of testosterone. Many transgender men do not menstruate, and those with male-range testosterone levels will experience an erythropoietic effect. As such an amenorrheic transgender man taking testosterone, registered as female and with hemoglobin/hematocrit in the range between the male and female lower limits of normal, may be considered to have anemia, even though the lab report may not indicate so. Conversely, the lack of menstruation, and presence of exogenous testosterone make it reasonable to use the male-range upper limit of normal for hemoglobin/hematocrit. Using the male-range upper limit of normal for alkaline phosphatase and creatinine may also be appropriate for transgender men due to increased bone and muscle mass, respectively. In these cases the provider should reference the male normal ranges for their lab.[19]

Table 3. Lower and upper limits of normal to use when interpreting selected lab tests in transgender men using masculinizing hormone therapy

Lab measure	Lower Limit of normal	Upper Limit of normal
Creatinine	Not defined	Male value
Hemoglobin/Hematocrit	Male value if amenorrheic*	Male value
Alkaline Phosphatase	Not defined	Male value

* If menstruating regularly, consider using female lower limit of normal.

Individualized dosing based on patient centered goals

Some patients may desire limited hormone effects or a mix of masculine and feminine sex characteristics. Examples include deepening of voice or growth of a beard (both irreversible), with retention of breasts or female body habitus. Some patients may choose to undergo testosterone therapy for a period of time to develop such irreversible changes, and then discontinue testosterone and revert to their endogenous estrogen hormonal milieu. While manipulation of dosing regimens and choice of medication can allow patients to achieve individual goals, it is important to have a clear discussion with patients regarding expectations and unknowns. Specifically, it is not possible to prospectively choose a regimen that will predictably allow patients to arrive at a specified configuration of sex characteristics. Furthermore, individual genetic and physiologic variation can result in wide variations in blood levels and response to therapy between different individuals using the same route and dose. The best approach in these cases is to start with low doses and advance slowly, titrating to effect. At the same time, response to hormone therapy is also individualized and measures such as beard growth or voice changes are variable in both degree and time course. Likely predictive factors of speed and degree of virilization include genetics and particulars of body habitus; younger age at start also likely contributes to faster progress and a greater degree of virilization once an endpoint is reached. Patients beginning hormone therapy later in life may experience more limited results. Patients should be counseled on setting reasonable expectations based on these factors, and avoid making comparisons to the experiences of others. Anecdotal sources suggest that maximal virilization may occur within 2-5 years.[20]

Specific considerations and conditions

Pelvic pain and persistent menses (/guidelines/pain-transmen) are covered elsewhere in these guidelines.

Post-gonadectomy: Since testosterone dosing should be based on physiologic male replacement levels, no reduction in testosterone dosing is required after gonadectomy. Some patients may choose to use a lower dose, which is appropriate as long as dosing is adequate to maintain bone density, however they should be informed of possible reduced muscle mass, energy and libido. Adequacy of dosing in those on low testosterone replacement post gonadectomy may be assessed by following LH and FSH levels and titration of dosing to maintain these in the premenopausal range.[21]

Erythrocytosis/polycythemia: Hemoglobin and hematocrit (H&H) values in transgender men should be interpreted in the context of the dose of testosterone used and menstruation status. Transgender men with physiologic male testosterone levels and who are amenorrheic would be expected to have H&H values in the male normal range. Note this may differ from the normal female range listed on the lab report if the patient is registered in the lab system as a female. Providers should reference their lab(s)' normal male range H&H, and disregard reported high flags if an amenorrheic transgender man on testosterone has an H&H above the female upper limit, but below the male upper limit. Similarly in

this same patient, an H&H below the male lower limit but above the female lower limit may not be flagged as abnormal, but in reality may represent a true anemia. Patients with persistent menses or on lower doses of testosterone should have their H&H interpreted accordingly. Transgender men with true polycythemia should first have their testosterone levels checked, including a peak level, and have dose adjusted accordingly. Changing to a more frequent injection schedule (maintaining the same total amount of testosterone over time) or transdermal preparations may limit the risk of polycythemia.[16] Phlebotomy or blood donation may be an appropriate short term solution depending on the level of elevation; in all cases other pathologic causes of polycythemia should be excluded. In addition to neoplasms and cardiopulmonary disease, specific conditions of concern in transgender men include obesity-related obstructive sleep apnea, and tobacco use.

Older transgender men: Older transgender men: No upper age limit exists for testosterone replacement in non-transgender men.[22] As such, there is no age recommendation for the termination of testosterone therapy in transgender men. It is reasonable to consider discontinuing hormone therapy at or around age 50, the age at which non-transgender women undergo menopause. Regardless of the presence of gonads at this age, withdrawal of testosterone will result in reduced muscle mass, body hair and libido.

Autoimmunity: There is a certain but incompletely defined linkage between sex hormones and autoimmune conditions. Testosterone has been associated with overall immune suppression, and autoimmune conditions are more common in non-transgender women than men.[23] Testosterone deprivation results in an increased Th1:Th2 ratio.[24] However the relationship is more complex, as demonstrated by the paradoxical improvements seen in multiple sclerosis during pregnancy.[23] Patients with autoimmune conditions should be informed that their condition could potentially worsen (or improve) once virilizing therapy has begun. Hormone dosing should begin low and advance slowly, monitoring for worsening symptoms, and in collaboration with any specialists who may be managing the autoimmune condition.

Migraine: Migraines have a clear hormonal component and relationship to estrogen. Given the persistence and possible fluctuation of estrogen levels in many transgender men taking testosterone, migraines may be precipitated or exacerbated in the context of testosterone therapy. Patients with a history of migraines should consider starting with a low dose and titrating upward as tolerated. Transdermal testosterone may be preferred to avoid any potential cyclic effect associated with injected testosterone.[25]

Mental health conditions: While hormones may contribute to mood disorders (such as in premenstrual dysphoric disorder or postpartum depression), these is no clear evidence that testosterone therapy is directly associated with the onset of or worsening of mental health conditions. In fact it has been found that transgender men experience improvements in social functioning and reduced anxiety and depression once testosterone therapy is begun.[26,27] Mental health conditions in transgender men

should be approached with a broad differential diagnosis as in any other patient, taking caution to avoid relating all symptoms directly to gender dysphoria or testosterone therapy. Consider using a non-injected medication form to avoid the potentially cyclic levels, which could bring about or worsen existing mood symptoms.

Testosterone therapy in patients with a prior history of cancer: An active sex hormone-sensitive cancer is an absolute contraindication to testosterone therapy. For patients with a prior history of hormone sensitive cancer (i.e. breast), consultation with an oncologist is recommended.

Hair Loss: Hair loss may begin soon after beginning hormone therapy, and is dependent on genetic factors. There are two patterns of hair loss seen in transgender men; Frontal and temporal recession, and male-pattern baldness (receding at the forehead and thinning at the crown). Both forms may cause alarm for patients, and in some cases result in a desire to discontinue therapy. Patients should be counseled prior to initiation of therapy on the risk, unpredictable nature, extent and time course of this condition. Management is similar to that in non-transgender men. Over the counter minoxidil, 5-alpha reductase inhibitors, and surgical approaches may be used. The 5-alpha reductase inhibitor finasteride blocks conversion of testosterone to the potent androgen dihydrotestosterone.[28] Finasteride 1mg daily (Propecia) is approved for male pattern baldness, while the 5mg daily dose (Proscar) is approved for management of prostatic hypertrophy.[29] Side effects may include reduced libido or sexual dysfunction, though impact on erectile function (manifesting as genital engorgement) may be less relevant for transgender men who have not undergone metoidioplasty. In general, the 1mg daily dose has minimal sexual side effects. The negative impact on results of 5-alpha reductase inhibition on transgender men early in their course of testosterone therapy is unknown. As with non-transgender men, use of the 5mg daily dose of finasteride, or use of the more potent 5-alpha reductase inhibitor dutasteride, may result in excessive testosterone blockade, and resultant sexual side effects and regression of some virilization.

Metabolic syndrome and related conditions (obesity, hyperlipidemia, impaired glucose tolerance, polycystic ovarian syndrome/PCOS): Cardiovascular (/guidelines/cardiovascular) and diabetes (/guidelines/diabetes) considerations are covered elsewhere in these guidelines. Polycystic ovarian syndrome can manifest with any combination of impaired fasting glucose, dyslipidemias, hirsutism, obesity, and oligo- or amenorrhea with anovulation. Some of these features (hirsutism, oligo- or amenorrhea) may be welcomed by transgender men and present prior to testosterone administration. Testosterone administration is not contraindicated in the presence of PCOS, but patients should be monitored for hyperlipidemia and diabetes. Transgender men with amenorrhea in the presence of testosterone are not believed to be at elevated risk of endometrial hyperplasia, due to the atrophic effects of testosterone on the endometrium (Grading T O M).[30,31] It may be prudent to pursue endometrial evaluation prior to initiation of testosterone in transgender men with a current history of amenorrhea/oligomenorrhea. Testosterone replacement in non-transgender men is associated with an increased risk of obstructive sleep apnea (OSA).[22] It is unknown whether OSA is increased in

transgender men after the initiation of testosterone. However, the behavioral health improvements seen with testosterone therapy may result in positive lifestyle changes that reduce obesity, disorders of glucose metabolism, or hyperlipidemia. In all but the most severe cases (diabetes out of control, active unstable coronary artery disease), transgender men should be informed of risks, and if testosterone therapy continues to be desired, it should be continued with concurrent conventional management of metabolic disorders and their sequelae (Grading: X C S).

Metabolic syndrome and related conditions (obesity, hyperlipidemia, impaired glucose tolerance, polycystic ovarian syndrome/PCOS): Cardiovascular and diabetes considerations are covered elsewhere in these guidelines. Polycystic ovarian syndrome can manifest with any combination of impaired fasting glucose, dyslipidemias, hirsutism, obesity, and oligo- or amenorrhea with anovulation. Some of these features (hirsutism, oligo- or amenorrhea) may be welcomed by transgender men and present prior to testosterone administration. Testosterone administration is not contraindicated in the presence of PCOS, but patients should be monitored for hyperlipidemia and diabetes. **Transgender men with amenorrhea in the presence of testosterone are not believed to be at elevated risk of endometrial hyperplasia, due to the atrophic effects of testosterone on the endometrium (Grading T O M).**[30,31] It may be prudent to pursue endometrial evaluation prior to initiation of testosterone in transgender men with a current history of amenorrhea/oligomenorrhea (/guidelines/pain-transmen). Testosterone replacement in non-transgender men is associated with an increased risk of obstructive sleep apnea (OSA).[22] It is unknown whether OSA is increased in transgender men after the initiation of testosterone. However, the behavioral health improvements seen with testosterone therapy may result in positive lifestyle changes that reduce obesity, disorders of glucose metabolism, or hyperlipidemia. In all but the most severe cases (diabetes out of control, active unstable coronary artery disease), transgender men should be informed of risks, and if testosterone therapy continues to be desired, it should be continued with concurrent conventional management of metabolic disorders and their sequelae (Grading: X C S).

Acne: Acne of the face and body are common side effects of virilizing hormone therapy. Approach to symptom management is consistent with established practices in non-transgender people. Patients can be reassured that acne tends to peak in the first year of testosterone therapy, and then declines.[32] Maintaining physiologic testosterone levels, and avoiding excessive peaks associated with prolonged injection dosing intervals may help minimize acne.

Hormone therapy information for patients

- Testosterone hormone therapy overview (/patients/information-testosterone-hormone-therapy)

About consent forms for hormone therapy:

Informed consent is a process which occurs between a patient and a provider. The process should include an individualized discussion of the risks, benefits, unknowns, alternatives, and risk of no treatment. We are no longer recommending the use of consent forms for hormone therapy. Many other common interventions such as contraception or HIV pre-exposure prophylaxis do not involve the use of consent forms, and rely on a discussion and shared decision making between patient and provider. If the informed consent process is properly documented in the chart, consent forms do not likely provide any additional legal protections to the provider. Elimination of consent forms helps to demystify and destigmatize hormone therapy. Providers can use the information provided in these guidelines to frame their individualized discussions with patients.

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Medical Referral Disclaimer

The CoE is unable to respond to individual patient requests for medical guidance. If you need medical advice, please contact your local primary care provider. If you need clarification, seek a second opinion locally or have your provider contact us for more information.

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