Masculinizing Hormone Therapy
Protocol for Care of Transmasculine Patients
## Table of Contents

- Cedar River Clinics Model 3
- Patient Education for Informed Consent 3
- Relative and Absolute Contraindications for Hormone Therapy 4
- Moving Towards Evidence Based Practice 5
- Effects of Hormone Therapy 6
  - Physical Changes 6
  - Emotional Changes 7
- Fertility and Sexual Health 8
- Health Risks and Side Effects of Hormone Therapy 9
- Informed Consent Process 11
- Initiation of Hormone Therapy 13
  - Initial Visit 13
  - Second Visit 15
  - Third Visit (Injection Only) 16
- Hormone Administration 16
  - Routes of Testosterone Administration 16
  - Tailoring Medications to Risk Factors 17
  - Common Regimen 17
- Monitoring and Follow Up 19
  - Follow Up Schedule 20
- Preventive Care While on Hormone Therapy 21
- Discontinuation of Hormone Therapy 22
- Additional Resources 22
- Sources 22

*The content contained in this peer-reviewed toolkit and its documents is intended as general guidance for medical providers and does not constitute legal or medical advice.*
Cedar River Clinics Model

The Cedar River Clinics Model is a method of providing trans* healthcare that incorporates the best available evidence, respect for patient autonomy, comprehensive patient education, shared decision making, and informed consent.

The following recommendations for managing hormone therapy have been cultivated and modified based on the efficacy, safety, and patient satisfaction verified during an ongoing analysis of the Cedar River Clinics Model and in conjunction with the most recently published information on trans* health. References available at the end of this module.

Patient Education for Informed Consent

Adequate patient education is critical for informed consent and to ensure patient safety while undergoing masculinizing hormone therapy. The contents of this module can serve as a guide for patient education. In addition, it is particularly important for the patient to understand the following:

- Responses to hormone therapy are individualized. Hormone therapy will impact different people in different ways and patients must agree to:
  - Take medications only as prescribed
  - Take medications only in the correct dosages
  - Take only their own medications
  - Communicate with their provider if they are unhappy with their course of masculinization

- Continuing care and routine visits with a healthcare provider are required when on hormone therapy. Patients must understand and agree that:
  - In the first year of hormone therapy, frequent visits with their healthcare provider are necessary for monitoring hormone therapy responses, dosage, and side effects.
  - Complete annual physical exams are a requirement for hormone treatment.

- Good communication is required when on hormone therapy.

  It is important that patients communicate honestly with providers about their complete health history, including all substance use and current or past use of self-managed hormone or feminizing supplements. Conversely, it is important for providers to give patients assurance that they will not be denied treatment based on revelations of self-managed hormone use or substance use.

Ensure that the patient has ample opportunity to ask clarifying questions and that all questions and concerns have been addressed. During the course of hormone therapy, make sure patients know to alert you about:
- Side effects or adverse reactions
- Dissatisfaction with the testosterone therapy
- Concerns or questions about the therapy
- Any supplement, drug, or medication use
- Any self-managed hormone or masculinizing supplement use
- Any deviations from prescribed plan

Advise patients that the body may convert excess testosterone into estrogen if taking a higher than recommended dose; as such, taking more than the prescribed amount of testosterone can be counter-productive to the masculinization process.

- Pace and duration of therapy may be longer than expected or desired

Patients need to understand that it may take several months before the masculinizing effects of the testosterone become noticeable and that it can take several years to complete the masculinization process. In addition, hormone therapy must be continued indefinitely if full masculinization is to be maintained.

**Relative and Absolute Contraindications for Hormone Therapy**

The presence of risk factors does not mean that testosterone therapy is contraindicated. Proper monitoring and an emphasis on patient education should be employed to minimize risks without denying treatment for most conditions.

There are few absolute contraindications for testosterone therapy. These contraindications are:

- Inability to give informed consent
- Pregnancy

Presence of any other comorbid conditions does not automatically rule out therapy as an option, but may require further evaluation and management to ensure patient safety. Referral to an appropriate mental health provider or other specialist may be necessary prior to, or concurrent with, starting testosterone therapy.

Risk factor associated with adverse events while on hormone therapy include:

- Liver disease
- Dyslipidemias
- Untreated hypertension
- History of venous thrombosis
- Smoking
- Untreated mental illness
- Family history of heart disease
- Family history of breast cancer
- Polycythemia

Providers should not deny access to hormone therapy based on the presence of any of these comorbid conditions. The Hormone Administration section below includes guidance on decreasing risk of adverse effects with certain comorbid conditions.

**Moving Towards Evidence Based Practice**

Both providers and patients need to understand that there is a limited evidence base for transgender health generally and hormone therapy specifically. While this is frustrating, we are fortunate to have standards of care and best practices that have been built on at least 60 years of clinical practice in the United States (and even longer in Europe). These best practices provide excellent guidance for care.

The guidelines and recommendations in this module are based, in part, on this legacy of cumulative knowledge and rely heavily on the efforts of The Center for Excellence in Transgender Health, which has culled available evidence into easily accessible practice documents. These recommendations are also based on the level of patient satisfaction and therapy effectiveness experienced at the Cedar River Clinics.

Given the lack of Level 1 (highest level) evidence for initiation and management of hormone therapy, it should be understood that:

- Hormone therapy for gender affirmation has not been well studied.
- The effects of the hormone therapy may be beneficial, damaging, or both.
- Individualized responses to hormone therapy are difficult to predict.
Effects of Hormone Therapy

Physical Changes

Patients need to understand that hormone therapy will cause many physical changes, some of which may be desired and some of which may not. Certain changes will be permanent and others will be reversible if hormone therapy is discontinued.

The Endocrine Society’s table below provides a quick overview of changes associated with masculinizing hormone therapy.

**TABLE 13. Masculinizing effects in FTM transsexual persons**

<table>
<thead>
<tr>
<th>Effect</th>
<th>Onset (months)</th>
<th>Maximum (yr)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin oiliness/acne</td>
<td>1–6</td>
<td>1–2</td>
</tr>
<tr>
<td>Facial/body hair growth</td>
<td>6–12</td>
<td>4–5</td>
</tr>
<tr>
<td>Scalp hair loss</td>
<td>6–12</td>
<td>^2</td>
</tr>
<tr>
<td>Increased muscle mass/strength</td>
<td>6–12</td>
<td>2–5</td>
</tr>
<tr>
<td>Fat redistribution</td>
<td>1–6</td>
<td>2–5</td>
</tr>
<tr>
<td>Cessation of menses</td>
<td>2–6</td>
<td>^3</td>
</tr>
<tr>
<td>Clitoral enlargement</td>
<td>3–6</td>
<td>1–2</td>
</tr>
<tr>
<td>Vaginal atrophy</td>
<td>3–6</td>
<td>1–2</td>
</tr>
<tr>
<td>Deepening of voice</td>
<td>6–12</td>
<td>1–2</td>
</tr>
</tbody>
</table>

1 Estimates represent clinical observations.
2 Prevention and treatment as recommended for biological men.
3 Menorrhagia requires diagnosis and treatment by a gynecologist.


Permanent effects of hormone therapy include:

- Significant enlargement of the clitoris (although note that clitoral size will reduce somewhat if hormone therapy is discontinued)
- Male pattern hair loss
- Facial hair growth
Deepening of the voice (although vocal tone may become somewhat higher if hormone therapy is discontinued)

Increased body hair growth

Non-permanent effects that may return to a feminized state if hormone therapy is discontinued include:

- Redistributed body fat
- Increased muscle development
- Increased energy levels
- Increased acne
- Increased red blood cells
- Amenorrhea
- Anovulation
- Thinning of the vaginal wall

Limitations of Masculinizing Hormone Therapy

- Overall masculinization
  Patient goals for masculinization vary. Many patients desire to be consistently perceived as male in all contexts. For some patients, this will be possible. For others, hormone therapy alone will not allow for this degree of masculinization. Help patients set realistic expectations for the effects and timeline for hormone therapy.

- Height
  Hormone therapy does not cause significant changes in height.

- Breast size
  Testosterone will not have an impact on breast size or composition.

- Clitoral growth
  Significant clitoral growth will occur with hormone therapy. Some patients will be satisfied with the growth achieved; others will want to consider metoidioplasty or phalloplasty.

**Emotional Changes**

Masculinizing hormone therapy can have an impact on one’s “emotional landscape,” including greater extroversion, less somatization, decrease in affective intensity (mood swings), increased libido, heightened anxiety, and greater contentment.
• It is difficult to separate which emotional responses are attributable to testosterone and which are associated with increased comfort with one’s body.
• Mood appears to most affected at the beginning and end of dosing for injected testosterone.
• Although increased aggression has been historically associated with testosterone use, this does not appear to be a common side effect in those who do not have a history of poor impulse control or co-existing mental illness.

Providers need to:
• Screen for pre-existing mood disorders or mental health issues.
• Assist with finding coping strategies as needed.
• Ensure access to mental health provider and support services as needed.

Fertility and Sexual Health

Hormone therapy causes significant changes to fertility, sexual function and libido.

Changes that may impact sexuality and sexual function:
• Vaginal atrophy may cause discomfort and require artificial lubrication with penetrative sex.
• Vaginal atrophy may cause increased risk for STIs and protection should be encouraged.
• Increased libido and sex drive.
• Changes in sexual interest and orientation are possible.

Fertility should be discussed in detail, including the following:
• Fertility in transgender men has not been well studied.
• Hormone therapy may lead to permanent infertility, although many transmen have become pregnant after temporary cessation of testosterone therapy.
• Hormone therapy is not a guaranteed form of birth control; barrier methods and progesterone-only methods can be utilized to protect against unintended pregnancy.
• Egg storage should be offered to all patients, although it is often considered prohibitively expensive and invasive.
• Patients who desire to conceive may stop testosterone at any time to attempt to conceive. There is no research to guide expectations on 1) if or when normal menses will resume, 2) if or when conception will occur, or 3) if a certain hormone-free interval is advisable before trying to conceive. Data is conflicting on whether androgenization of a female fetus occurs with exposure to high levels of testosterone.
Additionally, hormone therapy does not protect against HIV and other STI’s. Barrier methods and proper sex toy hygiene are important for reducing risk of infections.

**Health Risks and Side Effects of Hormone Therapy**

Testosterone therapy may increase risks for certain diseases, conditions, and cancers; it may also cause unpleasant side effects. Discuss this in detail and ensure that all questions regarding level of risk, anticipated schedule for monitoring those risks, and prevention strategies are answered. More detailed explanation and discussion regarding the health risks and side effects of masculinization hormone therapy can be found at (link to WPATH SoC version 7 here). Below is an overview of these risks.

The risks associated with testosterone therapy are significantly increased with:

- Age >35
- High blood pressure
- History of blood clots
- Family history of breast cancer
- Pre-existing risk factors for cardiac, cardiovascular, and metabolic disorders

**Health Risks**

**Cancer**

Cancer risks with testosterone therapy are uncertain at this time. Excess testosterone stored in the endometrium and fatty breast tissue may be converted into estrogen, increasing the risk of breast and endometrial cancer. On the other hand recent research has been reassuring; particularly research suggesting that atrophy of the endometrial lining in transgender men on testosterone therapy is common and could be protective. As such, providers should:

- Encourage breast and pelvic health maintenance per current guidelines.
- Obtain a thorough family and personal health history.
- Discuss potential increased cancer risk with patients.
- Advise patients that any spotting or menstrual bleeding after the onset of amenorrhea should be reported immediately to the healthcare provider.
- Advise patients that taking higher than recommended doses of testosterone can increase risks for cancer and decrease the masculinizing effects of hormone therapy.
Liver Disease

Testosterone therapy can cause transient elevations in liver enzymes with a slight increased risk for liver disease. Liver enzyme monitoring is prudent prior to the initiation of hormone therapy and periodically during hormone therapy.

Hypertension

Taking testosterone may increase blood pressure but does not appear to increase risk for hypertension in the absence of other predisposing factors such as family history of hypertension or personal history of PCOS. If there is preexisting hypertension and it is controlled with medications and/or diet and exercise, closer monitoring may be required in order to take testosterone safely. Healthy diet and exercise can decrease these risks.

Dyslipidemia

Testosterone therapy can alter cholesterol levels to those of a natal male:

- HDL levels may decrease
- LDL levels may increase
- May increase risk for heart attack and stroke
- Healthy diet and exercise are important for decreasing these risks

Diabetes

Testosterone therapy can increase the risk of Type 2 diabetes if other risk factors such as significant weight gain and history of PCOS are present.

Polycythemia

An increase in the rate of blood cell production is a very common side effect of testosterone therapy (Hct > 50%) and:

- May decrease the effectiveness of circulation due to increased viscosity
- May increase risk for thrombosis
- May increase risk for heart attack and stroke
- Regular blood donation can be an effective management strategy for testosterone-induced polycythemia.
- Obtain routine CBC’s to monitor RBC levels
Common Side Effects

**Increased Weight**

Testosterone therapy may cause an increase in weight and visceral fat if not accompanied by changes in diet and exercise. However, research has demonstrated that weight, adiposity and BMI alone are not adequate measures of health status. As with all patients, health at every size should be encouraged in patients undergoing hormone therapy, and health status while on hormone therapy should be based on appropriate assessments such as lipid status and glucose control.

Patients may need to increase their protein intake during early transition to accommodate muscle development.

**Acne**

May be severe enough to cause scarring and require medical intervention.

**Vaginal Atrophy**

Testosterone therapy may cause dryness and thinning that result in pain or bleeding with vaginal penetration. This may require use of lubricants or topical estrogen depending on severity of symptoms and sexual practices.

**Informed Consent Process**

Informed consent is an important part of the healthcare process and is required before beginning hormone therapy. Informed consent requires an assessment of the patient’s mental capacity and their ability to make complex medical decisions. It is important that the patient understands and can verbalize the limitations, side effects, permanency, and health risks associated with hormone therapy. There are several approaches to the informed consent process:

- **Two Visit Protocol**

  This protocol involves an initial one-hour visit to establish care, complete patient education, assess for gender dysphoria, and assess the patient’s ability to give consent. This is followed by a second one-hour visit to review labs and complete a physical exam before providing prescriptions for gender affirming hormones. This protocol requires that the primary provider have an ability to assess for gender dysphoria, mental capacity, and co-occurring mental health conditions. The two visit protocol falls within the World Professional Association of Transgender Health (WPATH) standards of care. The following criteria should be met prior to initiating hormone therapy:

  - Persistent, well-documented gender dysphoria
  - Capacity to make a fully informed decision and to give consent for treatment
- Age of majority or supportive guardian who will co-sign consent forms
- The presence of co-occurring mental health conditions is not a barrier to starting hormone therapy as long as the patient is able to give consent and an appropriate management plan is in place.

- Expedited Therapy Protocol

This protocol uses the “two visit protocol” above, with the addition of the patient providing an “ICATH” letter at the time of first visit. This letter results from an in-depth one-time visit with a mental health professional competent in gender issues. This protocol allows for expedient access to gender affirming care and accommodates the variable levels of comfort each primary provider has with mental health and mental capacity assessments. This protocol falls within the WPATH standards of care.

Informed Consent for Access to Trans Health (ICATH) is a website that offers an explanation of the informed consent model and a letter template for providers. This letter stipulates that the patient has been deemed mentally competent to make medical decisions and has expressed an informed desire to seek gender-affirming care. This template was created in response to the WPATH Standards of Care recommendation for a letter to be provided by a mental health provider prior to initiating gender affirming hormone or surgical care.

Link to sample ICATH letter: [http://www.icath.org/default.html](http://www.icath.org/default.html)

- Standard Therapy Protocol

The standard therapy protocol is based on long-time WPATH recommendations for a step-wise approach to allowing gender affirming care. This approach requires a letter of referral from a mental health care professional. Historically this process could be expected to take 3-6 months before a letter of referral was granted and hormone treatment could begin. The latest version of the WPATH Standards of Care recognizes that primary care providers are capable of managing appropriate counseling and mental health screenings for their patients.

- Harm Reduction Protocol

The harm reduction protocol states that patients actively undergoing self-managed hormone therapy at time of intake should be managed differently than a new patient and are not subject to the two visit protocol. The rationale behind this protocol is that the patient is already undergoing hormone therapy with possibly unsafe medications and should not be removed from therapy because this may cause more emotional and/or physical harm than the continuation of current treatment. In addition, immediately switching to legal pharmacy-obtained medication promotes safety. Harm reduction standards for this protocol are as follows:

- Complete all initial visit screening, patient teaching, lab draws
- Complete physical exam with initial visit
- Obtain informed consent with initial visit
- Continue current hormone treatment at safe doses at time of initial visit
- Further assess need for dosage adjustments based on clinical, medical, and lab results at next visit
- Closely monitor for possible harmful effects of self-dosing

Cedar River Clinics recommends the two-visit protocol or the expedited therapy model based on provider experience and comfort. It is important to remember that delays in accessing gender-affirming care may be socially or emotionally detrimental to many patients.

**Initiation of Hormone Therapy**

The following is based on a two-visit protocol and can be tailored as needed to other models of care. Additional customization may be required for providers outside of the United States.

**Initial Visit**

**Patient Interview**

Complete medical, mental health, surgical history with special attention to:

- Mental health concerns
- Past Surgeries
- Hyperlipidemia
- Cardiovascular disease
- PCOS
- Diabetes
- Liver disease
- Family/personal history of estrogen-dependent cancers
- Social history with special attention to diet, exercise, and smoking
- Past gender affirming treatments and surgeries
- Full family medical history

**Physical Examination**

- Vital signs
- Height and weight
Lab Screenings

Required lab work:

- Fasting lipids
- Fasting complete metabolic panel
- CBC

Preferred additional lab work:

- Serum free testosterone
- STI testing per current CDC recommendations
  - Note: The CDC does not offer a specific recommendation for STI testing in tranmasculine patients. Testing should be based on sexual practices.

Patient Education

- Elicit patient goals and expectations for physical and emotional changes.
- Inform patient about side effects of hormone therapy, both desired and undesired.
- Inform patient about potential impacts on health and wellness tailored to patient’s medical history:
  - Worsening hyperlipidemia
  - Obstructive sleep apnea
  - Acne
  - Increased risk for CV disease
  - Diabetes
- Discuss potential impacts on fertility and options for becoming a parent.
- Offer smoking cessation counseling if applicable.
- Discuss potential social consequences.
- Discuss anticipated schedule for well-person and gender affirming care during hormone therapy.
- Discuss potential occupational consequences.
- Discuss potential impact on familial relationships.
- Discuss potential impact on romantic relationships.
- Discuss anticipated medical and non-medical expenses.
- Discuss potential impact on emotional health and review of available resources.
Documentation

- Complete comprehensive chart note including findings of mental health assessment.
- Assessment notes should include documentation of persistent gender dysphoria.

Billing

- In the past, providers have used the code for Endocrine Disorder NOS in order to assure access to care in a hostile insurance climate, and out of ethical objection to using diagnoses which pathologize transgender people. In the changing insurance climate, using this generalized code has actually become a barrier to care. With patient consent, it may be most appropriate and strategic to use the ICD-10 Gender Identity Disorder code (F64.1). It is important to discuss this with patients, and to clarify that you as a provider do not consider their gender identity pathological. If patients are opposed to the use of this code in their medical records, Endocrine Disorder NOS could be used.
- Consider billing by time
- Use CPT code 99203 or 99213 (or higher as needed based on complexity of exam, data reviewed, and comorbidity).

Second Visit

Patient Interview

- Review lab results.
- Discuss impact of findings on health status.

Physical Examination

- Vital signs
- Height and weight
- Palpate thyroid
- Auscultate heart and lungs
- Assess extremities for signs of circulatory compromise
- Assess gait as a component of mental health screening

Patient Education

- Reinforce healthy diet and regular physical exercise.
- Create plan for management of health conditions and health risks as needed.
- Reinforce smoking cessation and provide resources if needed.
• Review medication doses and plan for titration.
• Demonstrate injection technique for injectable testosterone and offer additional return appointments for patient demonstration.
• Provide written materials about safe testosterone injection.
• Review routine well-person healthcare visit expectations and scheduling for patients on hormone therapy.

Documentation

• Comprehensive chart note
• Findings of physical exam
• Signed consent form
• Coding same as for visit one, with addition of general physical exam V70.0

Third Visit (Injection Only)

A visit with an RN/MA/health worker is indicated for patients who will be using injectable testosterone. This visit should be scheduled once patient has medication and supplies “in-hand” from the pharmacy. The patient should be taught and be able to demonstrate proper self-injection technique. Provide written information on self-injection technique and safe sharps disposal.

Hormone Administration

Routes of Testosterone Administration

There are a number of routes by which patients can take testosterone, including intramuscular or subcutaneous injections, gels, patches, and implants.

Injectable Testosterone

Injection is the most common and least expensive route of hormone administration. Intramuscular injection has historically been recommended. However, at least one study on testosterone treatment of hypogonadal cisgender men have shown that it is safe, effective, more comfortable, and more convenient to use subcutaneous injections. Many providers have begun to recommend this route. Other providers avoid the subcutaneous route secondary to frequent complaints of local site reactions. For subcutaneous injection, needles should be 25 gauge - a smaller gauge can 1) cause difficulty drawing up the thick testosterone oil preparation and 2) cause unnecessary trauma to tissues by injecting the preparation with too much pressure. Needle length varies based on body habitus but an average length would be a 5/8
tuberculin needle.

Careful patient teaching is required for patients who are self-injecting because the dose may be confusing. Express doses to patients as mL to inject, with injection amount based on the specific concentration of the preparation prescribed.

Transdermal

Gels and patches are an effective but expensive route of hormone administration. They also result in a slower onset of physical changes. For these reasons, they are much less commonly used. Patients who do opt for transdermal administration require careful patient teaching to prevent the accidental transfer of testosterone to others. It is especially important to prevent transfer to children.

Implants

Implants offer a long-term and slow-release route of hormone administration with less abrupt hormonal shifts. However, implants are quite expensive and require a minor in-office surgical procedure approximately every 3 months. For this reason, implants are much less commonly used than other forms of testosterone administration.

**Tailoring Medications to Risk Factors**

For patients with concerning risk factors, it may be prudent to start at a lower dose and/or titrate more slowly depending on the severity of the risk factors listed below.

- Hypertension
- Hyperlipidemia
- Pre-existing metabolic, cardiac, or cardiovascular conditions
- Liver diseases or disorders
- Other complicating factors that increase individual health risk levels

**Common Regimen**

Injectable Route

- Testosterone cypionate 200 mg/mL in sesame or cottonseed oil. Prescribe alternative oil for suspension if patient has an allergy.
- Administer via intramuscular or subcutaneous route
- Dosing:
Some patients appreciate a process of dose titration, while others prefer to immediately begin testosterone at a full dose. In most cases it is safe to start at a full dose.

- If titrating, start at an initial dose of 50 mg every week or 100 mg every two weeks; after 4 to 6 weeks, increase dose to 100 mg every week or 200 mg every two weeks.
- After about two years, titrate down to lowest dose required to keep free testosterone in target range.
- Post oophorectomy, use lowest testosterone dose required to keep free testosterone in target range and recommend calcium and vitamin D to preserve bone density. Some patients will continue to require a full dose.

*Note: testosterone supplementation is required on a permanent basis post oophorectomy*

**Transdermal**

There are several options for transdermal therapy.

- **Androgel**
  - 1% formulation: 2.5 g packets (25 mg testosterone) and 5 g packets (50 mg testosterone), pump bottle delivering 12.5 mg testosterone per actuated pump
  - 1.62% formulation: 1.25 g packets (20.25 mg testosterone), 2.5 g packets (40.5 mg testosterone), pump bottle delivering 20.25 mg testosterone per actuated pump
  - Initiate at 50 mg per day; titrate to 100 mg per day after 4 to 6 weeks.
  - Apply to shoulder, uppers arms, or abdomen once daily in the morning.
  - Wash hands carefully after application and cover the skin on which gel was applied to prevent transfer to others.

- **Androderm**
  - Available in 2 mg and 4 mg patches
  - Initiate at 2 mg each evening (remove before placement of next patch); titrate to 4 mg each evening after 4 to 6 weeks. Max dose 6 mg.
  - Apply patch to shoulder, uppers arms, or abdomen once daily in the morning.
  - Site must be rotated, with 7 days between using a patch at the same site.
  - Avoid showering, baths, and swimming for 3 hours after application.
  - Best sites of application are the back, abdomen, upper arms, and thighs.
  - Patch should not be applied to bony areas.

- Compounding pharmacies can prepare tailored creams or gels.
• Post oophorectomy, use lowest testosterone dose required to maintain free testosterone in target range and recommend calcium and vitamin D to preserve bone density. Some patients will continue to require a full dose.

**Monitoring and Follow Up**

It is important to monitor response to hormone therapy through regularly scheduled follow-up visits to:

• Assess patient satisfaction with therapy.
• Assess efficacy.
• Address any questions or concerns.
• Monitor lab work.
• Provide preventive screenings.
• Provide continued support and referrals as needed.

**Hormone Level Monitoring**

Serum hormone levels are a useful quantitative tool for assessing masculinization, and many patients find these lab values reassuring. Overall, hormone levels should fall in the normal physiologic range for a male of the patient’s age. If the patient is happy with masculinization without reaching typical male ranges, this is not concerning. Patient satisfaction and safety (i.e. avoiding supraphysiologic testosterone levels and subsequent polycythemia) are the primary goals of treatment. Guidelines for evaluating hormone levels are as follows:

• Total testosterone: 350-700 ng/dL (at mid cycle if using injectable testosterone)
  • If testosterone level is significantly above a normal male range, the patient’s dose should be reduced and a CBC should be draw to assess for polycythemia.
  • It is not typically useful to evaluate estradiol level in masculinizing patients.

**Choosing Reference Ranges for Other Labs**

There are no strict guidelines for determining when to use a male reference range or a female reference range when evaluating laboratory findings in masculinizing patients. Knowledge of physiology and using a gestalt approach will guide decision making. For example, when testosterone is in a male range, hematocrit and hemoglobin will be elevated about a female range and male reference ranges should be used to assess for polycythemia.
Follow Up Schedule

One month after initiation of hormone therapy

- In-person visit
- Assessment for mood changes
- Assess blood pressure

Three months after initiation of hormone therapy:

- In-person visit
- Assessment for mood changes
- Serum free testosterone, trough (preferred but not required)

Six months after initiation of hormone therapy:

- In-person visit
- Assessment for mood changes
- CBC
- Serum free testosterone (preferred but not required)

One year after initiation of hormone therapy:

- In-person visit
- Fasting complete metabolic panel
- Fasting lipids
- Serum free testosterone (preferred but not required)
- Assessment for mood changes

After one year of therapy:

- Annual exam with appropriate labs and assessment (See Cedar River Clinics’ FTM Annual Exam module)
- Pelvic care if indicated
Preventive Care While on Hormone Therapy

Pap Smears:

Pap smears will continue to be necessary even after initiation of testosterone therapy.

- Anyone with a cervix needs to have regular pap smears with timing based on current guidelines.
- If post hysterectomy and positive history of HSIL or greater, patient will require pap of vaginal cuff on regular schedule until 3 WNL results in a row.
- If post hysterectomy and no hx HSIL or greater, no further pap smears are required.
- Pap smears offer an opportunity for STI screening; however, vaginal GC/CT screening can also be completed without exam using urine or self-collected vaginal swab.

Additional planning may be needed for conducting pap smears in transgender men, particular those on testosterone therapy. Patients may experience heightened emotional distress and anxiety in regard to pelvic exams, and building rapport is a critical step in ensuring patient well being. Additionally, patients may experience physical pain with pelvic exam due to atrophic tissue and, in some cases, rare vaginal penetration. Sexual practices range widely among transgender men; some patients may engage in receptive vaginal intercourse routinely, while for others the pap smear may their first ever experience of vaginal penetration. Rates of unsatisfactory pap results are also higher in transgender men, possibly due to tissue atrophy.

Strategies for improving pap smear outcomes and patient experience of pelvic exam include:

- Use of oral anxiolytics to decrease procedural anxiety.
- Short course of vaginal estradiol prior to exam to repair atrophic tissue.
- Application of a topical anesthetic such as lidocaine at time of exam to prevent pain.
- Use of a smallest speculum possible.
- Use of an adequate amount of water-based lubricant.
- Using several different types of collection devices to increase likelihood of obtaining adequate endocervical sample (i.e. collect a total of three samples using a brush, a broom, and a spatula).

Chest Care:

Testosterone therapy may increase risk for breast cancer although this has not been verified in studies.

- Clinical breast exams will continue to be necessary regardless of surgical status.
- Mammograms will continue to be necessary per current guidelines if any breast tissue remains.
- Mammograms may be necessary for patients with full double mastectomies/chest reconstruction and a family or personal history of breast cancer since cancer can form and grow on the chest wall.
Bone Density:

Risk factors for osteoporosis are dependent on length of testosterone therapy and the presence or absence of gonadal tissue.

- If on testosterone for > 5 years, order DEXA scan if > 50 yo
- If on testosterone < 5 years, order DEXA scan if > 60 yo

Colorectal Cancer:

Use usual screening guidelines.

**Discontinuation of Hormone Therapy**

In the event that a patient decides to discontinue hormone therapy or presents with a clinical reason for discontinuation, they should be supported in this decision. Patients may prefer to titrate their dose down prior to cessation, but this is not required. It is safe to discontinue testosterone at any time.

**Additional Resources**

Hormone Therapy Monitoring Cheat Sheet - [http://CedarRiverClinics.org/TransToolkit/CheatSheets](http://CedarRiverClinics.org/TransToolkit/CheatSheets)
Annual Exam for Female to Male Patient - [http://CedarRiverClinics.org/TransToolkit/PreventiveCare](http://CedarRiverClinics.org/TransToolkit/PreventiveCare)
Surgical Care Guide - [http://CedarRiverClinics.org/TransToolkit/PostSurgicalCare](http://CedarRiverClinics.org/TransToolkit/PostSurgicalCare)

**Sources**


