U.S. Department of Justice
Federal Bureau of Prisons

Health Services Division *Washington, D.C. 20534*

June 1, 2023

MEMORANDUM FOR ALL CLINICAL DIRECTORS
ALL HEALTH SERVICE ADMINISTRATORS
ALL INSTITUTION CHIEF PHARMACISTS

FROM: (b)(6); (b)(7)(C) D.O., Medical Director
Health Services Division

SUBJECT: Clinical Guidance on Gender-Affirming Care of Transgender and Gender Nonbinary Persons

The Health Services Division (HSD) has revised the Clinical Guidance on Gender-Affirming Care of Transgender and Gender Nonbinary Persons, June 2023. The guidance is issued for immediate implementation throughout the Bureau of Prisons (BOP). They will soon be available on SallyPort and bop.gov.

This clinical guidance was previously issued in 2016 as the Medical Management of Transgender Inmates. The revised document includes addition of a transition pathway for guidance in decision making, changes to language consistent with updated guidelines and BOP policy. Finally new sections were added regarding preventative health screening, non-invasive or invasive surgical procedures and transitions of care.

Thank you for your ongoing commitment to providing quality health care to the BOP patient population. If you have any questions regarding this guidance, please contact CDR (b)(6); (b)(7)(C) (b)(6); (b)(7)(C) at (b)(6); (b)(7)(C) @bop.gov.

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GENDER-AFFIRMING CARE OF TRANSGENDER AND GENDER NONBINARY PERSONS

Federal Bureau of Prisons

Clinical Guidance

June 2023

WHAT'S NEW IN THIS DOCUMENT

This guidance on *Gender-Affirming Care of Transgender and Gender Nonbinary Persons* is an update to the BOP Clinical Guidance on *Medical Management of Transgender Inmates*, issued in December 2016. Significant changes were made throughout this document to more closely align with community standards and the World Professional Association for Transgender Health (WPATH) *Standards of Care for the Health of Transgender and Gender Diverse People, Version 8* published in 2022. While WPATH Standards of Care were referenced when updating this guidance, deviations due to the unique correctional environment were made when necessary. The key revisions include:

- Addition of *Transition Pathway for Transgender Inmate Patients* for guidance in patient care decisions found in *Section 4* and *Appendix 1.*
- Added language in *Section 5* to describe the process for requesting designation to a cross/gender reaffirming institution according to BOP policy.
- New sections created with emphasis on care in correctional environment:
  - Preventative Health Screening (*Section 13*)
  - Minimally or Non-Invasive (*Section 14*) and Invasive [Surgical] Procedures (*Section 15*)
    - Information regarding facial hair removal expounded *(Facial Hair Removal)*
    - Including description of the use of Transgender Utilization Review Advisory Group
  - Transitions of Care (*Section 16*)

DOCUMENT ORGANIZATION

- The **ABBREVIATIONS** are now listed in a new section, *Key to Abbreviations*, preceding the appendices. (This list does not replace the list of *Definitions* in *Section 2.*)
- The appendices summarizing **HORMONE TREATMENT** have been renumbered, as follows:
  - *Appendix 2. Summary Charts for Feminizing Hormone Therapy*
  - *Appendix 3. Summary Chart for MASCULINIZING Hormone Therapy*
- The main body of the **MEDICATION MONITORING** guidance is now in two new appendices:
  - *Appendix 4. Monitoring During FEMINIZING Hormone Therapy*
  - *Appendix 5. Monitoring During MASCULINIZING Hormone Therapy*
- The items in the *References* section are now listed alphabetically by author or source.

TABLE OF CONTENTS

1. PURPOSE

The Federal Bureau of Prisons (BOP) Clinical Guidance for *Gender Affirming Care of Transgender and Gender Nonbinary Persons* provides recommendations for the medical management and treatment of transgender and gender nonbinary federal inmates, referred to in this guidance as *transgender* and/or *gender nonbinary* and *individual(s)*, *patient(s)*, or *person(s)*.

2. DEFINITIONS

BISEXUAL: Refers to a person attracted to both sexes.

BIGENDER: Refers to those who identify with two genders or multigender.

BOP TRANSGENDER CLINICAL CARE TEAM: A group of physicians (primary care and psychiatrists), pharmacists, and social workers devoted to advocating and advancing the treatment options for this population. The team provides education and the tools to institutional staff to develop clinical treatment plans for the TG and gender nonbinary population. This team has no authority to review, approve or disapprove gender affirming surgery referrals.

BOP TRANSGENDER EXECUTIVE COUNCIL (TEC): A group of BOP management personnel who mitigate executive level administrative gender affirming issues.

BOP TRANSGENDER UTILIZATION REVIEW ADVISORY GROUP : A group of BOP physicians, psychiatrists, pharmacists, and social workers assigned by the Medical Director to provide clinical review of gender-confirming surgical requests.

CISGENDER: denoting or relating to a person whose sense of personal identity and gender corresponds with their sex assigned at birth.

COMPLEX AND INVASIVE GENDER CONFIRMING PROCEDURES: complex and invasive medical procedures will almost always require general anesthesia, and a surgeon with advanced skills. Most of these procedures carry the inherent risk for blood loss, infection, pain, multi-day hospitalization, and post-operative complications; in this guidance, these terms refer to all procedures listed in *Table 5*, which require the approval of the Medical Director.

FEMALE-TO-MALE (FTM): Refers to a biological female who identifies as, or desires to be, a member of the male gender. The term **transgender male**, or **trans male** for short, is used to refer to the **GENDER IDENTITY** of a person who is **FTM**. (See the definition of **TRANSGENDER** below.)

GAY: Refers to a person who is romantically or sexually attracted to persons of the same gender. The term is mostly used to describe males. (See the definition of **LESBIAN** below.)

GENDER-AFFIRMING HORMONES: Hormonal therapy utilized to facilitate physiological change(s) during **TRANSITION** (see definition below). The term **CROSS-SEX HORMONES** is often utilized in the medical literature, but it is falling out of use.

GENDER-AFFIRMING SURGERY/GENDER-CONFIRMING SURGERY: The surgical component of an individual's **TRANSITION** (see definition below); these terms have replaced the outdated terminology of **SEX REASSIGNMENT SURGERY**.

GENDER BINARY: A system of viewing gender as consisting solely of two, opposite categories of gender, termed "male and female"

GENDER CONFORMITY: Behavior and appearance that adheres to the social expectations of a particular **GENDER**. (See the definition of **GENDER NONCONFORMITY** below.)

GENDER DYSPHORIA (GD): The condition of feeling that one's emotional and psychological identity as male or female is different from one's biological sex assigned at birth. **GD implies that there is a state of distress or anxiety directly related to this conflict.** In the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5)*, released in May 2013, people whose assigned sex at birth is contrary to the one they identify with *and* who are experiencing a state of distress should be diagnosed with **GD**.

- *This diagnosis of **GD** is a revision of the criteria in the DSM-IV for **GENDER IDENTITY DISORDER (GID)** and is intended to better characterize the experiences of affected individuals. The DSM-5 no longer uses the term **GID**.*
- *A Gender Dysphoria diagnosis may be necessary in some regions to access transition-related care.*

GENDER EXPRESSION: Includes mannerisms, clothing, hair style, and choice of activities that individuals use to express their **GENDER IDENTITY**.

GENDER FLUID: A changing or "fluid" gender identity.

GENDER IDENTITY: How one identifies oneself: female, male, both, or neither. **GENDER** encompasses aspects of social identity, psychological identity, and human behavior.

GENDER NONBINARY: someone who does not identify as exclusively male or female

GENDER NONCONFORMITY (ALSO KNOWN AS GENDER NONBINARY): Behavior or appearance that does not adhere to the social expectations of a particular **GENDER**.

GENDER QUEER: Denoting or relating to a person who does not subscribe to conventional gender distinctions but identifies with neither, both or a combination of male and female genders.

INFORMED CONSENT: A patient's ability to understand the risks, benefits, alternatives, unknowns, limitations, and risks of treatment pertaining to a specific healthcare intervention.

INTERSEX: Refers to a person whose sexual/reproductive anatomy or chromosomal pattern does not seem to fit the typical biological definition of male or female.

LESBIAN: Refers to a female who is romantically or sexually attracted to other females.

MALE-TO-FEMALE (MTF): Refers to a biological male who identifies as, or desires to be, a member of the female gender. The term **transgender female**, or **trans female** for short, is used to refer to the **GENDER IDENTITY** of a person who is **MTF**. (See the definition of **TRANSGENDER** below.)

MINIMALLY INVASIVE GENDER AFFIRMING PROCEDURES: minimally invasive medical procedures are usually same day office or hospital-based procedures that may require anesthesia and break skin or enter an organ; in this guidance, this term refers to professional facial hair removal services, and other procedures typically labeled as aesthetic in a non-trans population.

NON-INVASIVE GENDER AFFIRMING TREATMENT MODALITIES: non-invasive medical modalities typically do not break skin or enter a body part; in this guidance, this term refers to treatment modalities such as voice and communication training.

PATIENT-CENTERED CARE: Care in which patients are partners with their health care providers and health care decisions are driven by the patient's specific health needs and desired health outcomes.

SEX: A biological classification based on chromosomal composition, reproductive anatomy (primary sex characteristics), and the phenotypic characteristics that develop during pubertal maturation (secondary sex characteristics).

SEXUAL ORIENTATION: The direction of one's sexual interest. It is not defined by the person's gender identity. People of the same gender identity may have different sexual orientations.

TRANSGENDER (TG) (ALSO KNOWN AS TRANSSEXUAL) OR TRANS SPECTRUM: An umbrella term used for individuals whose **GENDER IDENTITY** does not conform to the typical expectations associated with the gender they were assigned at birth. It is important to note that terminology changes often and the latter term is falling out of use.

TRANSPHOBIA: Dislike of or strong prejudice against transgender people with attitudes such as fear, discomfort, distrust, or disdain.

TRANSITION: The period during which **TG** individuals change their physical, social, and legal characteristics to the gender with which they identify. **TRANSITION** may also be regarded as an ongoing process of physical change and psychological adaptation. Individuals may want to proceed to different stages of transition.

3. INTRODUCTION & GENERAL CONSIDERATIONS

TRANSGENDER (**TG**) people are those whose gender identity is different from the sex which they were assigned at birth. **GENDER DYSPHORIA** (**GD**)—previously known as **GENDER IDENTITY DISORDER** (**GID**)—is the *discomfort or distress* caused by a discrepancy between a person's gender identity and that person's gender assigned at birth.

- TG people have many of the same health needs as the general population. They may also have other special healthcare needs.
- Not all TG person(s) will be diagnosed with GD, and a diagnosis of GD is not required for access for all TG services. According to the American Psychological Association's guidelines (see *References* section), an individual's identification as **TG or GENDER NONBINARY** can be healthy and self-affirming and is not considered pathological.
- However, some **TG or GENDER NONBINARY** individuals experience distress associated with their gender identity, their body, or their sex assigned at birth. There is also distress associated with

societal stigma and discrimination. A systematic review of studies by Valentine, et al (2018) indicates significantly higher rates of mental health morbidity compared with the general population—particularly anxiety, depression, and suicidality.

- **Gender-affirming health care involves supporting individuals through social, psychological, behavioral, or medical (including hormonal treatment or surgery) treatments—to support and affirm an individual's experienced gender identity.**

The **BOP TRANSGENDER CLINICAL CARE TEAM** . The team provides education and the tools to institutional staff to develop clinical treatment plans for the TG and gender nonbinary population. This team has no authority to review, approve or disapprove gender affirming surgery referrals. This team is composed of physicians (primary care physicians and psychiatrists), pharmacists, and social workers who are available to help institution providers. For example, when patients have medical contraindications (relative or absolute) to hormone treatments, consultation with the TCCT may be helpful. Institution staff may refer to their Regional Medical Director for a list of current team members and their contact information.

STIGMA

Stigma and prior negative experiences in institutions can contribute to healthcare disparities. Stigma commonly leads to prejudice and discrimination, which may also exacerbate mental health concerns in transgender and gender-nonconforming individuals.

Respect and trust are essential to the provider-patient relationship. Respectful language and terms should always be used, affirming the patient's experienced gender identity. Once an individual has identified as **TG**, use of pronouns or salutations preferred by the **TG** individual is appropriate, especially for those patients with a Case Management Activity (**CMA**) Sentry assignment of **TRANSGENDER** (either TRN M2F or TRN F2M; see ***TABLE 1*** below). This practice is more likely to facilitate a cooperative relationship between the **TG** individual and others, and generally reduces the stress of gender transition.

➔ *Using this informal approach is distinct from a legal name change while in BOP custody; a legal name change must conform to the policy requirements in the* ***Program Statement 5800.15 Correctional Systems Manual*** *(or the most recent version).*

MENTAL HEALTH CONCERNS AND SUICIDALITY

As reported by Valentine, et al (2018), a higher prevalence of depression, anxiety, and suicidality is seen among TG adults compared to the general population. It has been suggested these elevated rates are linked to complex trauma, stigma, violence, and discrimination. A recent study by Baker, et al (2021) suggests that appropriate gender-affirming care, including medical and surgical care, can lessen psychiatric symptoms. Transgender adults with **GD** are at an increased risk of suicidal ideation and suicide prior to initiation of their gender transition, regardless of the clinical endpoint of their transition - whether that endpoint is living as the psychologically identified gender, hormone therapy, cosmetic treatments, breast augmentation/removal, and/or gender-affirming surgery (Wolford-Clevenger et al 2018). For many individuals, the risk of suicide may decrease after receiving the appropriate, individualized treatment (Turban et al 2022).

COMORBID CONDITIONS

- **Anxiety and Depression:** The most common mental health conditions seen in **TG** adults are anxiety and depression. A significant interdisciplinary approach between Psychology and Health Services is always required for **TG** patient care.
  - ➔ *See BOP Program Statement 5310.16, Treatment and Care of Inmates with Mental Illness, available at https://www.bop.gov/policy/progstat/5310_16.pdf.*
- **HIV Infection:** Epidemiologic studies indicate a higher prevalence of HIV in the **TG** populations, specifically among **transgender male** persons. HIV services for TG people should address the specific biological, pathological, and social needs of this population (i.e., antiretroviral therapy, HIV prevention and care programs). Effective risk assessment requires obtaining an accurate sexual risk history, including anatomy-specific sexual behavior.
  - ➔ *See CDC's website on HIV and Transgender People, listed in the References section.*

PATIENT-CENTERED MULTIDISCIPLINARY TREATMENT APPROACH

A patient-centered multidisciplinary team approach is recommended for managing issues associated with the incarceration of TG individuals. Incarcerated individuals may present to an institution with a well-established gender identity or begin their transgender or gender nonbinary journey while incarcerated. It is important to have a system in place to allow for individualized treatment. Individuals requesting care for gender dysphoria should have access to a diverse range of treatment services. Patient-centered care explores individualized therapeutic options, which may differ from person to person.

The BOP offers **TRAUMA-INFORMED CORRECTIONAL CARE (TICC),** which incorporates an understanding that patient attitudes, behaviors, and concerns are likely to be affected by prior traumatic experiences. **TICC** includes both training and treatment programs, emphasizes the recognition of trauma in all forms, and incorporates the principle that all staff may have a role in reducing its impact.

HOUSING ASSIGNMENTS, PROGRAM ASSIGNMENTS, AND PAT SEARCHES

- ➔ *Refer to the current version of BOP **Program Statement 5324.12, Sexually Abusive Behavior Prevention and Intervention Program**, available at https://www.bop.gov/policy/progstat/5324_012.pdf*
- ➔ *Refer also to the BOP **Program Statement 5200.08 Transgender Offender Manual**, available at https://www.bop.gov/policy/progstat/5200-08-cn-1.pdf*

PRISON RAPE ELIMINATION ACT (PREA)

Per the national Prison Rape Elimination Act (PREA) Resource Center, *being transgender is a known risk factor for being sexually victimized in confinement settings.* Consequently, PREA regulations and BOP Program Statements provide ways to protect the transgender population through the following:

- **PREA** regulations, incorporated into **Program Statement 5324.12, Sexually Abusive Behavior Prevention and Intervention Program** (available at *https://www.bop.gov/policy/progstat/5324_012.pdf),* state that the intake screening shall assess the individual's risk of sexual victimization by considering, at a minimum, whether the individual is known or perceived to be gay, lesbian, bisexual, **TG**, intersex, or gender nonconforming.
- According to the PREA (*28 C.F.R. § 115.41 (h)*), *individuals may not be disciplined for refusing to answer, or for not disclosing complete information in response to,* [questions about being gay, lesbian, bisexual, **TG**, intersex, or gender nonconforming].
- According to the PREA (*28 C.F.R. § 115.15 (e)*), *staff shall not search or physically examine a transgender or intersex inmate for the sole purpose of determining the inmate's genital status. If the inmate's genital status is unknown, it may be determined as appropriate during conversations with the inmate, by reviewing medical records, or, if necessary, learning that information as part of a broader medical examination conducted in private by a medical provider.*

4. TRANSITION PATHWAY FOR TRANSGENDER PATIENTS

Appendix 1 summarizes a pathway for TG patients to access gender-affirming mental health and medical care in the BOP. The order depicted in this table is not as important as the provision of individualized treatment, e.g., individuals may approach a medical professional before they approach a mental health professional and this should not preclude them or delay appropriate treatment if the medical provider is qualified in this area.

A gender dysphoria (GD) diagnosis is not necessary for hormone treatment, and TG patients may not be interested in following up with a mental health professional. However, the reverse might also occur: TG patients may seek out a mental health professional for months before they are ready to be referred for a medical evaluation. Not all gender non-binary patients will require gender-affirming hormone treatment and treatment is individualized to the patient's needs.

5. DESIGNATION TO A CROSS/GENDER-AFFIRMING INSTITUTION

In accordance with ***Program Statement 5200.08 Transgender Offender Manual***, transgender individuals may ask their respective warden to be considered for designation to a gender-affirming institution. All requests for designation are reviewed by the Transgender Executive Council (TEC). The memo is submitted from the Warden to the TEC indicating the patient is requesting re-designation to an institution able to provide full-time gender affirming life experiences in identified gender.

6. PRESENTATION OF GENDER NON-CONFORMITY

Gender non-conformity status is based on an individual's experienced gender identity, role, or expression differing from societal norms assigned to a particular sex. When an individual self-identifies as TG and requests referral or evaluation for treatment, an evaluation is conducted according to PS5200.08, and further referrals may be made, as clinically appropriate, to fully evaluate the individual's treatment needs.

Discussion of the following areas may be useful in helping a person describe their gender identity:

- Persistent and marked differences between experienced gender and their biologic or natal sex.
- Strong feelings about primary or secondary sex characteristics.
- Strong feelings about being treated as or becoming another gender.
- Belief that one's actions, feelings, or mannerisms are more characteristic of another gender.

Gender non-conformity often (but not always) presents with gender dysphoria, which denotes the discomfort or distress that is caused by the nonconformity of a person's gender identity, and that person's sex assigned at birth. Gender nonconformity may present in a spectrum of expressed or desired gender affirmation needs. Patients may experience:

- Strong desires to be treated as the identified gender
- Strong convictions that one has feelings and reactions typical of the identified gender
- Strong inclinations to look in a way that affirms the identified gender

Clinicians must accurately assess and document the patient's individual presentation. Attention should be given as to whether the level of distress meets criteria for a formal diagnosis of gender dysphoria, and/or if there are other coexisting mental or medical health disorders.

7. GENDER-AFFIRMING MENTAL HEALTH ASSESSMENT

When TG individuals present to mental health professionals it is important to conduct a thorough mental health evaluation. The mental health professional is encouraged to affirm the individual's experienced gender and whether there is gender dysphoria. The mental health professional should conduct a thorough evaluation including assessing for any mental health diagnosis. The clinician will develop an individualized treatment plan for the TG patient and collaborate with the medical provider.

A mental health assessment for TG individuals typically includes:

- Obtaining a gender identity history and screening for **GD**
- Screening for other mental health disorders related to mood, anxiety, autism, eating, personality, psychosis, and substance use
- Identifying a history of abuse or neglect
- Assessing any current or past self-harm ideations or attempts
- Performing an assessment of affective, cognitive, and psychosocial functioning
- Psychosocial treatment recommendations; and/or
- Medical referral, if indicated.

➔ *Please also refer to the APA's Guidelines for Psychological Practice with Transgender and Gender Nonconforming People, listed in the References section.*

MENTAL HEALTH TREATMENT CONSIDERATIONS

The mental health team plays an important role in gender-affirming care. This can include screening for mental health disorders and assisting with treatment planning. Prior to engaging in treatment, conversations regarding the individual's realistic expectations of outcome are encouraged to identify realistic goals for treatment.

➔ *A collaborative approach with both mental health and medical services staff is highly recommended.*

Patients can also be referred to psychiatry services for mental health concerns or medication management of mental illness.

- **PSYCHOTHERAPY:** This is a general term for treating mental health problems; it includes a broad variety of techniques to help individuals with emotional difficulties or coexisting mental illnesses. Psychotherapy can be used to learn about and treat an individual's moods, thoughts, and behaviors. It can also be supportive to individuals experiencing distressing thoughts, feelings and/or behavior.
- **PSYCHIATRY SERVICES:** Individuals can also be referred to psychiatry services for mental health concerns or medication management of other mental illness in conjunction with **GD**. Appropriate pharmacotherapy is considered when indicated to optimally manage co-existing mental health concerns prior to, or concurrently with, treatment of **GD**.

GENDER DYSPHORIA (GD) CRITERIA

Individuals identifying as TG or gender nonbinary do not necessarily have GD. Although data regarding the prevalence rates of **GD** in the transgender population is limited, many clinicians anecdotally report that most **TG** individuals experience some degree of dysphoria in the absence of treatment.

Because untreated or under-treated **GD** is associated with increased morbidity and mortality (Jackson et al 2023), screening for **GD** in **TG** individuals is essential. Without treatment, this population may experience higher rates of depression, anxiety, self-harm, and suicidality. Gender-affirming treatment supports TG people throughout their lifespan. Treatment modalities are designed to meet the individual's unique goals and may include social supports, mental health treatment, and medical treatment (including hormone therapy and surgery). These interventions may improve medical and psychological health, increase social support, decrease **GD**, treat mental health comorbidities, and improve TG individuals' overall quality of life**.** The DSM-5 criteria may be used to make the diagnosis of GD.

➔ *Refer to The American Psychiatric Association A Guide for Working With Transgender and Gender Nonconforming Patients for guidance on diagnosis of GD.*

8. GENDER-AFFIRMING MEDICAL ASSESSMENT

A MEDICAL EVALUATION should include:

- **Thorough review of all co-occurring medical conditions and whether they are reasonably controlled.**
  - ➔ *Comorbidities are not necessarily a contraindication to therapy and must be assessed for each patient. See more about drug risks in* Table 2 *(Feminizing Therapy) and* Table 3 *(Masculinizing Therapy).*
- **Review of any mental health evaluations and coordination with mental health care providers.**
- **Physical Examination:** Healthcare providers should utilize a gender-affirming approach, including using the individual's preferred name and pronouns during each clinical encounter. This also includes using non-gender specific terminology (ex. genital instead of penis/vagina or chest instead of breast) for anatomical body parts or asking if the patient has a preferred term to be used. The physical exam should only be performed on parts of the body indicated for the medical reason for the specific visit.
- **Documentation of Previous Treatment:** Hormonal therapy, surgery, etc.
- **Informed Consent:** Individuals must be counseled on the risks and long-term effects of hormonal therapy. Use of gender-affirming hormones in the management of **TG** individuals is considered an off-label use and does not currently have FDA approval but is considered a community standard. Due to the irreversibility of some of the treatment options and the side effects, the individual's informed consent is required before initiating treatment and must be documented within the medical record.
  - ➔ *See Section 9. Patient Education & Informed Consent.*
- **Contraindications and Precautions to Hormone Therapy:**
  - ➔ *See also the Summary Charts for Hormonal Therapy in Appendix 2. Feminizing Hormone Therapy and Appendix 3. Masculinizing Hormone Therapy for medication-specific contraindications.*

  FEMINIZING THERAPY
  - **CONTRAINDICATIONS:** Current diagnosis of estrogen-sensitive cancer (e.g., breast cancer); current diagnosis of thromboembolic disease (may consider after subspecialty consultation)
  - **PRECAUTIONS:** History of estrogen-sensitive cancer or history of thromboembolic disease should prompt referral to expert specialist prior to initiation of therapy. Presence of liver, kidney, or heart disease/stroke (or risk factors for heart disease such as high cholesterol, diabetes, obesity, smoking); retinal vascular thrombosis, history of macroprolactinoma, strong family history of breast cancer or thromboembolic disease; gallbladder disease.

MASCULINIZING THERAPY

- **CONTRAINDICATIONS:** Pregnancy; breast feeding; trans men with current carcinoma of the breast
- **PRECAUTIONS:** Erythrocytosis (hematocrit >50%) History of breast or uterine cancer (testosterone may have anti-proliferative effects on most, but not all cancers-referral to expert specialist recommended prior to initiation of therapy). Androgen-sensitive epilepsy; migraines; sleep apnea; depression; cardiac failure; renal failure or severe hypertension susceptible to salt retention and fluid overload; significant liver disease; coronary artery disease (**CAD**) or risk factors for CAD; bleeding disorders (for injected testosterone); significant history of violent behavior.

ASSESSMENT & DOCUMENTATION OF ACCURATE EHR CODES

Appropriately diagnosing individuals as to their gender identity is imperative for accurate individual record keeping and continuity of care ensuring all individuals are receiving appropriate preventive and gender affirming care and management both as incarcerated individuals and upon release to their community. All BOP individuals who identify as **TG or gender nonbinary** or are identified by history or current presentation as **TG or gender nonbinary**, should be referred to appropriate mental health professionals and/or health service providers. Utilization of inclusionary diagnoses in the EHR helps clinicians provide patient-centered care and medical interventions specific to organs present and transgender care (e.g., a transgender male who has residual breast tissue or an intact cervix getting a mammogram or pap smear).

For purposes of providing appropriate medical treatment and management, all individuals who identify as **TG**—whether or not they are receiving hormone treatment—need to have an accurate diagnostic code entered into the EHR health problem list, as listed in *Table 1*.

TABLE 1. ICD-10 EHR DIAGNOSTIC CODES FOR TRANSGENDER AND GENDER NONBINARY INDIVIDUALS

BOP Transgender Determination	ICD-10 EHR Codes	Corresponding Sentry CMA Codes
Transgender/Gender Identity DO/Gender Dysphoria - male to female	F64.0F[1]	TRN M2F
Transgender/Gender Identity DO/ Gender Dysphoria - female to male	F64.0M[1]	TRN F2M
Transgender/Gender Identity DO-Other-questioning/queer	F64.8Q[2]	
Personal History of Sex Reassignment	Z87890[3]	

[1] Document the degree of distress or impairment in social, occupational, or other important areas of functioning.
[2] This respective code is to be applied to patients who may not have consolidated their gender identity (questioning), or who identified as gender fluid/queer.
[3] If an individual has undergone gender-affirming surgery, use code Z87890 (Personal History of Sex Reassignment) along with the appropriate F64 code above. Document the type of surgery in detail.

9. PATIENT EDUCATION AND INFORMED CONSENT

Patient education and informed consent are crucial to the treatment process.

- Consent forms for gender affirming hormone therapy are designed to guide counseling and can be found in *Appendix 6* and *Appendix 7*. The information in these appendices is not all-inclusive and providers may add information to this document as clinically appropriate. Individuals should be provided with ample time to review this information and have all questions addressed prior to signing the document. Informed consent must be documented within the EMR.
- Securing consent for gender affirming surgery is the responsibility of the surgeon. Once the individual is approved by the Medical Director for surgical intervention for the treatment of GD, surgeons are responsible for discussing different surgical techniques, advantages and disadvantages of each, limitations of the different procedures, and a frank discussion of all the inherent risks and complications to include their own complication rates with each procedure.

10. HORMONE THERAPY: ELIGIBILITY, GOALS, OVERVIEW

Hormone therapy is an important part of gender affirming care. Studies demonstrate improved satisfaction (in the range of 70–80%) as it relates to mental health, quality of life, and sexual function for **TG** individuals who are receiving gender affirming hormone therapy (Siira et al 2023).

After a thorough and individualized evaluation, the medical provider may initiate hormone therapy after the risks and benefits have been discussed with the individual.

➔ *Refer to the Endocrine Treatment of Gender-Dysphoric/ Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline for more detailed information.*

ELIGIBILITY AND READINESS FOR GENDER-AFFIRMING HORMONE THERAPY

Patients do not need to meet the DSM criteria for **GD** to initiate gender-affirming hormone therapy. The eligibility for gender-affirming hormone treatment can be achieved by confirming gender incongruence, verifying transition is clinically appropriate, and patient understands the risks, and benefits of treatment through completion of the *Mental Health Assessment* and/or the *Medical Assessment*.

➔ *Gender-nonconformity is based on the individual's self-report. Therefore, the history or subjective component of the evaluation serves as the primary source for identifying a person as TG.*

➔ *An important aspect of eligibility and readiness for gender-affirming hormone therapy while incarcerated is the understanding that fertility may be affected permanently. According to BOP* ***Program Statement 6031 Patient Care****: Inmates are not authorized for fertility preservation services (sperm or egg/banking), even when infertility is an expected side effect of medically necessary treatment e.g., chemotherapy, pelvic radiation, or gender affirming treatment. Inmates are not authorized to donate sperm or eggs.*

GENERAL GOALS OF HORMONE THERAPY

The goal of hormone therapy is to reduce characteristics of the natal sex and induce those of the identified gender, allowing individuals to project their **GENDER IDENTITY**. Hormone therapy is focused on

affirming a person's gender identity, which is not always binary. Patient-centered therapy is focused on meeting the patient's needs.

11. FEMINIZING HORMONE THERAPY

The goal of feminizing hormone therapy is generally to suppress male secondary sex characteristics and the development of female secondary sex characteristics. Most clinical studies and guidelines recommend combined therapy with an anti-androgen, estrogen, and sometimes a progestin adjunct.

EXPECTATIONS OF FEMINIZING HORMONE THERAPY

Prior to beginning treatment, patients should be educated on realistic expectations of results, as well as the timeline of when to expect them. Every case is different, and slow change can lead to frustration.

➔ *It is important to discuss realistic expectations with the patient to avoid any attempts to self-increase the dosage in hopes of speeding up results.*

- Within the first six months of treatment, changes may be seen in body fat redistribution, loss of muscle mass, breast growth (usually to Tanner stage 2 or 3), testicular atrophy, decreased erections, decreased sperm production, and a slowing of body/facial hair growth.
- The maximum effect of treatment may not be seen for more than two years.
- Treatment does not provide voice alteration.
- Feminizing hormone therapy may also bring about changes in emotional and social functioning.
- Most treatment results are reversible upon cessation of treatment, but breast growth is permanent, and infertility may be irreversible.
- Refer to *Figure 1* on for a general timeline of listed effects.

FIGURE 1. FEMINIZING EFFECTS IN TRANSGENDER FEMALES

Effect	Onset	Maximum
Redistribution of body fat	3–6 mo	2–3 y
Decrease in muscle mass and strength	3–6 mo	1–2 y
Softening of skin/decreased oiliness	3–6 mo	Unknown
Decreased sexual desire	1–3 mo	3–6 mo
Decreased spontaneous erections	1–3 mo	3–6 mo
Male sexual dysfunction	Variable	Variable
Breast growth	3–6 mo	2–3 y
Decreased testicular volume	3–6 mo	2–3 y
Decreased sperm production	Unknown	>3 y
Decreased terminal hair growth	6–12 mo	>3 y[a]
Scalp hair	Variable	—[b]
Voice changes	None	—[c]

Estimates represent clinical observations: Toorians *et al.* (149), Asscheman *et al.* (156), Gooren *et al.* (157).

[a]Complete removal of male sexual hair requires electrolysis or laser treatment or both.

[b]Familial scalp hair loss may occur if estrogens are stopped.

[c]Treatment by speech pathologists for voice training is most effective.

Note: Adapted from Table 13. Feminizing Effects in Transgender Females reprinted from Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society* Clinical Practice Guideline by W.C. Hembree, P.T. Cohen-Kettenis, L Gooren, S. E. Hannema, W. J. Meyer, M. H. Muran, S. M. Rosenthal, J.D. Safer, V. Tangpricha, G. G. T'Sjoen, 2017, The Journal of Clinical Endocrinology & Metabolism 102(11):1-35.

SERUM HORMONE LEVELS FOR FEMINIZING HORMONE THERAPY

GOAL LEVELS FOR MTF: Serum Estradiol 100-200 pg/ml and Serum Total Testosterone <50 ng/dl

- While the goal of gender affirming hormone therapy is to suppress male secondary sex characteristics, serum estradiol levels should not exceed those of a premenopausal cis female (200 pg/ml); doses used to achieve an adequate level may be significantly higher than those used in hormone replacement therapy in menopausal women.
- It is important to note there are individuals who do not require estradiol as part of their hormonal therapy regimen and do well on an anti-androgen therapy alone. Bone density considerations should be fully disclosed to the patient who is considering this approach.
- There are individuals who require very little estrogen to obtain desired body characteristics and adequately treat any presenting dysphoria/incongruence (in these cases, a specific hormone level is NOT the patient's goal. Hormone levels are monitored to assure the level does not exceed 200 pg/ml).
- **Patients should be treated with the lowest effective hormone doses.**
  - ***As stated above, estradiol levels should not routinely exceed a premenopausal level of 200 pg/ml.***
  - The same holds true for total testosterone levels. While the goal is <50 ng/dl, there is a subset of individuals who do poorly with levels below 35 ng/dl. The ideal levels for these individuals may be between 35–50 ng/dl.

➔ *Titration of dose is based on the individual's goals within the context of clinical response, hormone levels, and safety monitoring (e.g., risk factors such as smoking or renal function may warrant dose adjustments).*

The Endocrine Society recommends monitoring of hormone levels every 3 months, during the first year of therapy and/or when titrating treatment regimens or altering therapy before stabilization of dosages has been achieved. After the first year of therapy, hormone levels can be monitored every 6-12 months as clinically indicated.

➔ *The laboratory monitoring guide for feminizing hormone therapy is included in Appendix 4.*

DOSE TITRATION

The science and interpretation of serum hormone levels for TG individuals is evolving. Titration of hormone therapy doses should be driven by patient goals and clinical response per individual. Monitoring for potential medication sided effects and hormone levels are critical components of adjusting treatment.

- The recommended titration approach for patients includes increasing both estrogen and antiandrogen medication dosing to achieve desired physiological changes, but not to exceed the premenopausal cis female physiologic ranges (100–200 pg/mL).
- Another approach includes maintaining current physiologic estrogen dosing, titration of antiandrogen therapy, and the addition of a progestin, if appropriate.
- Regardless of initial dosing regimen utilized, dosages may be titrated upwards over 3–6 months.

FEMINIZING MEDICATIONS

➔ *See the Summary Tables for TRANSGENDER FEMALE Hormone Therapy in Appendix 2 for information on each of the medication groups below.*

ANTI-ANDROGENS

Anti-androgens reduce testosterone levels and allow estrogen therapy to be used in lower doses while still reaching a maximum effect. Medications with anti-androgen effects include spironolactone, finasteride, GnRH agonists, and progestins.

- **SPIRONOLACTONE** is a potassium-sparing diuretic that directly inhibits testosterone secretion and androgen binding to the androgen receptor. It is the most commonly prescribed anti-androgen for gender nonconforming individuals in the United States.
  - Spironolactone can suppress facial and body hair growth, male pattern baldness, libido, and sexually stimulated erections. It decreases symptoms of benign prostate hypertrophy (BPH) and can lead to modest breast growth.
  - Due to its diuretic effects, patients may also experience self-limited polyuria, polydipsia, or orthostatic hypotension.
  - ➔ *The use of spironolactone must be carefully monitored in renal insufficiency and is contraindicated in patients with a potassium value greater than 5.5 mEq/L. Spironolactone can cause severe hyperkalemia and hypotension. Caution should be used when prescribed in conjunction with angiotensin-converting enzyme (ACE) inhibitors or angiotensin-receptor blockers (ARBs). It is important to monitor potassium levels and blood pressure of individuals taking spironolactone.*
- **5α-REDUCTASE INHIBITORS (**finasteride and dutasteride) inhibit 5-alpha reductase, the enzyme responsible for converting testosterone to its potent form, dihydrotestosterone.
  - Per WPATH SOC 8, data on the use of these medications in trans feminine populations is very limited: *It is unclear whether this class of medication could have any clinical benefit in trans feminine individuals whose testosterone and dihydrotestosterone levels have already been lowered with estrogen and an antiandrogen. We [WPATH] therefore do not recommend their routine use in trans feminine populations.* Rare use may be indicated in specific clinical circumstances such as for patients unable to tolerate spironolactone and which GnRH antagonists are not indicated or available.
- **GNRH AGONISTS** (goserelin, nafarelin, and leuprolide) suppress pituitary gonadotropin levels and gonadal steroids. They are most often used in adolescents for suppression of puberty but can be used to decrease testosterone levels and the amount of estrogen needed to achieve targeted physical effects.
  - Primary utilization in adult patients is for those who are unable to tolerate spironolactone due to hyperkalemia, increased frequency of urination, and/or a reduction in blood pressure or those who have some other contraindication to spironolactone use.
  - GnRH agonists do not carry a risk of thromboembolic disease, but use can result in osteoporosis if doses of estrogen given concurrently are insufficient.

- The high cost to the patient upon release should be considered in those with proximal release dates.
- In cases of persistent elevations of testosterone despite maximized spironolactone dosing, adherence must be thoroughly evaluated prior to consideration of a GnRH antagonist. Directly observed therapy should be considered. If complete adherence is determined to exist and levels are still elevated beyond reason, autonomous endogenous production (i.e., tumor) should be considered and appropriate evaluation should be conducted.

- **PROGESTINS** are a group of hormones that include medroxyprogesterone. Use of medroxyprogesterone is controversial and not routinely recommended. It is purported to aid in breast development at a cellular level as well as mood management, but its effect is mainly on the uterus. Evidence as an effective agent in gender-affirming hormone therapy is lacking. Per WPATH: *there is currently insufficient evidence the potential benefits of progesterone administration outweigh the potential risks.* Additionally, an association between progesterone use in transgender woman and VTE has also been identified.
  - ➔ *Medroxyprogesterone treatment comes with risk of developing mood disorders (depression/ irritability), lipid abnormalities, weight gain, and edema. There is also a concern of increased cardiovascular risk.*

ESTROGENS

Estrogens are used to provide feminization in the form of physical appearance and sexual characteristics. Effects include development of breasts, redistribution of body fat, softening of the skin, shrinkage of the testes, and testicular atrophy. Many formulations of estrogen are available, including parenteral, transdermal, sublingual, and oral. Estrogen may have positive health effects more generally, including increased high-density lipoprotein, decreased low-density lipoprotein, and preservation of bone mineral density. *Table 2* below lists conditions that can be exacerbated by gender-affirming estrogen therapy.

TABLE 2. MEDICAL CONDITIONS REQUIRING INCREASED MONITORING WITH ESTROGEN THERAPY

Contraindications	
• Current thromboembolic disease (may consider after subspecialty consultation) • Current diagnosis of estrogen-sensitive cancer	• Unstable ischemic cardiovascular disease
Precautions (Consider Subspecialist Consult)	
• History of prolactinoma • Breast cancer (non-estrogen dependent) • Severe liver dysfunction *(transaminases >3x upper limit of normal)*	• Coronary artery disease • Cerebrovascular disease • Severe migraine headaches • Retinal vascular thrombosis
Precautions (Recommend Increased Monitoring)	
• Obesity • History of cigarettes, tobacco, other nicotine use • Migraines or epilepsy • Diabetes • History of thromboembolic disease	• High cholesterol • High blood pressure • Heart, liver, kidney, or clotting disease • Hypoparathyroidism • Porpyria

- All estrogens come with a risk of thromboembolism, but lower doses and transdermal formulations are considered safer and should be used in populations at higher risk of thromboembolism (>40 years old, smoker, obese, etc.). Aspirin therapy may be considered for those at higher risk of thromboembolic disease.
- Intramuscular (IM) injections can cause greater peaks and troughs in estrogen levels, causing more mood disturbances than oral and transdermal preparations, making oral and transdermal preparations preferable for some patients. Reductions in peak and troughs can be partially mitigated by more frequent dosing of the injections.
- Use of estrogen should be individualized and adjusted regularly, based on serum estradiol levels and individual-specific goals or concerns. Estrogen should be started at low doses and titrated up as needed, based on hormone levels as well as individual tolerance and goals. If discontinuation is necessary, consider tapering therapy to alleviate mood disturbances.
- In patients scheduled for surgery or an immobilizing event, the treatment team (i.e., assigned surgeon) should be made aware of current hormone therapy. Limited evidence suggests low risk for thrombotic events whether therapy is continued or temporarily held (Totaro et al 2021). An individualized risk assessment should be performed in determining the appropriate treatment plan.
- Estrogens are partially metabolized by CYP3A4 and interactions may occur with agents that inhibit or induce CYP3A4. Refer to current drug interaction references and/or a pharmacist for additional information.

➔ *Conjugated and synthetic estrogen formulations cannot be measured through serum estradiol concentrations and are no longer recommended for gender-affirming hormone therapy.*

➔ *Synthetic estrogens, especially ethinyl estradiol, have been shown to have a higher risk of thromboembolism and should be avoided. Patients entering the BOP on synthetic estrogens should be transitioned to a more appropriate formulation.*

MONITORING

Gender-affirming hormone therapy may have risks up to and equivalent of those associated with hormone replacement therapy in biological females. Appropriate monitoring is crucial.

- Weight, blood pressure, physical exams, risk factors, medications, complete blood counts, renal and liver function, and lipid and glucose metabolism should be monitored for all TG individuals receiving gender-affirming hormone therapy.
- In addition, individuals undergoing feminizing hormone treatment should be monitored for development of feminine characteristics, target blood levels, and any adverse effects of the medication.

➔ *Refer to Appendix 4. Monitoring During Feminizing Hormone Therapy for additional guidance regarding monitoring.*

12. MASCULINIZING HORMONE THERAPY

The goal of masculinizing hormone therapy is the development of male secondary sex characteristics and suppression/minimization of female sex characteristics; this is usually done by the administration of a testosterone formulation.

EXPECTATIONS OF MASCULINIZING HORMONE THERAPY

Prior to beginning treatment, patients should receive education on realistic expectations of the treatment results, as well as the timeline of when to expect them. Every case is different, and slow change can lead to frustration.

- Effects developing within the first 6 months of treatment (onset within the first 3 months) include body fat redistribution, an increase in libido, an increase in skin oiliness and acne, clitoral enlargement, vaginal atrophy, cessation of menses, and infertility. Maximum effect usually occurs in 1–2 years but may take up to 5 years in some cases.
- Effects developing in the 6–12 month time frame include increased facial and body hair, scalp hair loss, increased muscle mass and strength, and deepening of the voice. Maximum effect often occurring in 1–2 years.
- Uterine bleeding should cease within a few months of high-dose testosterone therapy, but treatments such as GnRH agonists, medroxyprogesterone, and endometrial ablation may be used to stop menses prior to starting testosterone therapy or to decrease estrogen levels, if not responding to standard treatment.
- Most effects are reversible upon cessation of treatment, but changes in hair, voice depth, and infertility may be irreversible.
- Refer to *Figure 2* below for a general timeline of listed effects.

FIGURE 2. MASCULINIZING EFFECTS IN TRANSGENDER MALES

Effect	Onset	Maximum
Skin oiliness/acne	1–6 mo	1–2 y
Facial/body hair growth	6–12 mo	4–5 y
Scalp hair loss	6–12 mo	—[a]
Increased muscle mass/strength	6–12 mo	2–5 y
Fat redistribution	1–6 mo	2–5 y
Cessation of menses	1–6 mo	—[b]
Clitoral enlargement	1–6 mo	1–2 y
Vaginal atrophy	1–6 mo	1–2 y
Deepening of voice	6–12 mo	1–2 y

Estimates represent clinical observations: Toorians *et al.* (149), Asscheman *et al.* (156), Gooren *et al.* (157), Wierckx *et al.* (158).

[a]Prevention and treatment as recommended for biological men.

[b]Menorrhagia requires diagnosis and treatment by a gynecologist.

Note: Adapted from Table 12. Masculinizing Effects in Transgender Males reprinted from Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society* Clinical Practice Guideline by W.C. Hembree, P.T. Cohen-Kettenis, L Gooren, S. E. Hannema, W. J. Meyer, M. H. Muran, S. M. Rosenthal, J.D. Safer, V. Tangpricha, G. G. T'Sjoen, 2017, The Journal of Clinical Endocrinology & Metabolism 102(11):1-35.

Serum Hormone Levels for Masculinizing Hormone Therapy

Goal levels for Masculinizing Hormone Therapy: Serum Estradiol <50 pg/ml and Serum Total Testosterone 320–1000 ng/dl

Goal treatment levels are serum estradiol <50 pg/ml and serum total testosterone 320–1000 ng/dl (male physiologic range; some sources quote a normal reference range of 400–800 ng/dl). If a peak total testosterone level is drawn for injectable testosterone, the level should not exceed 1,000 ng/ml. If total testosterone levels exceed this range, refer to a transgender clinical care team physician or pharmacist for guidance in adjusting therapy.

➔*Free testosterone level monitoring is rarely required during gender affirming treatment. Dose adjustments are based on Serum Total Testosterone levels.*

Masculinizing Hormone Therapy During Pregnancy

➔ *Gender-affirming hormone therapy is contraindicated during pregnancy.*

- While therapy may lead to potentially irreversible infertility, it does not function as contraception, and pregnancy is still possible during treatment. Precautions should be taken to avoid pregnancy during treatment.
- A pregnancy test is obtained prior to starting treatment for all individuals with childbearing potential.

Titration of Masculinizing Hormone Therapy

Titration of hormone therapy doses should be driven by patient goals and clinical response per individual, including hormone level and safety monitoring.

- Clinical response is measured objectively by the presence of amenorrhea by month 6 of therapy.
- Lab references for testosterone levels vary (e.g., 320–1000 ng/dl). However, TG men with levels on the lower end of the range may express concerns about slow progress in gender affirmation or may experience low energy, libido, or mood—and thus warrant increased doses.
- Titration of testosterone should be done slowly with close monitoring for adverse events. Evidence remains unclear on whether increased doses will have positive effects once testosterone levels are greater than the midpoint of the reference range.
- Daily testosterone levels in TG men do not fluctuate as they do in natal males; however, they may vary over the laboratory monitoring intervals.

MASCULINIZING MEDICATIONS

➔ *See the Summary Charts for MASCULINIZING Hormone Therapy in Appendix 3 for a full list of the different formulations of testosterone—including summarized information on dosing, adverse effects, contraindications, and interactions.*

➔ *Monitoring is covered in Appendix 5. Monitoring During Masculinizing Hormone Therapy*

TESTOSTERONE

Androgen supplementation is used to induce male sex characteristics, including cessation of menses, voice changes, increased facial/body hair growth, increased muscle mass, hairline recession/baldness, changes in sweat and odor patterns, and clitoral enlargement. Other effects include increased libido and energy. Vaginal dryness will also likely occur. Higher doses of testosterone may be needed for TG men than for natal males who are being treated for low testosterone.

- Several formulations are available, ranging from IM injections to transdermal patches and gels. Due to the classification of all testosterone preparations as DEA-controlled substances and their associated risk of potential abuse and/or diversion, in the correctional environment, injectable formulations are the preferred method of administration.
- The IM injections release slowly from the muscle but may induce cyclical adverse effects that coincide with varying plasma concentrations. This can be mitigated by using a lower dose of IM testosterone given one to twice weekly (rather than every two or more weeks).
- While oral formulations are available, they are not used, due to extensive liver metabolism and the associated potential for hepatic complications.
- Androgen use should be individualized and adjusted based on serum total testosterone levels, tolerance, efficacy, and patient goals. Dosing should start low and be titrated up to an appropriate level while keeping the dose as low as possible to minimize adverse reactions.
- Ovulation may still be possible even when undergoing long-term testosterone therapy. Therefore, it is possible for a transgender man to become pregnant.

PROGESTINS AND GNRH AGONISTS

Medroxyprogesterone and GnRH agonists are not routinely used but may be treatment options in individuals wishing to cease menstruation and decrease estrogen levels prior to testosterone treatment. These medications may also have a use in individuals receiving high-dose testosterone therapy who still experience uterine bleeding after the first few months of treatment.

DRUG RISKS

TABLE 3 lists conditions that can be exacerbated by gender-affirming testosterone therapy.

TABLE 3. MEDICAL CONDITIONS REQUIRING INCREASED MONITORING WITH TESTOSTERONE THERAPY

Contraindications	
• Pregnancy • Breastfeeding • Trans Men with carcinoma of the breast	
Precautions	
• Severe liver dysfunction (transaminases >3x upper limit of normal) • Breast or uterine cancer • Erythrocytosis (hematocrit >50%) • Androgen-sensitive epilepsy • Migraines • Sleep apnea • Depression or significant history of violent behavior	• Epilepsy • Renal failure • Severe hypertension susceptible to salt retention and fluid overload • Coronary artery disease (CAD) or risk factors for CAD • Bleeding disorders (for injected testosterone)

MONITORING

Masculinizing hormone therapy has the same risks associated with hormone replacement therapy in biological males. Appropriate monitoring is crucial.

The Endocrine Society recommends monitoring of hormone levels every 3 months, especially when titrating treatment regimens or altering therapy before stabilization of dosages has been achieved. Once stabilization of dosages has been achieved, hormone levels are typically done every 6-12 months or as clinically indicated.

- Weight, blood pressure, physical exams, risk factors, medications, complete blood counts, renal and liver function, and lipid and glucose metabolism should be monitored for all TG individuals receiving gender-affirming hormone therapy.
- In addition, individuals undergoing masculinizing hormone treatment should be monitored for development of masculine characteristics, target blood levels, and any adverse effects of the medication. Some of the adverse effects experienced with chronic testosterone therapy are erythrocytosis, liver dysfunction, hypertension, excessive weight gain, salt retention, lipid changes, excessive or cystic acne, and adverse psychological changes.

➔ *Refer to Appendix 5. Monitoring During Masculinizing Hormone Therapy for additional guidance.*

13. PREVENTIVE HEALTH SCREENINGS

Regardless of the patient's identified gender or gender-confirming procedures, if the patient has a particular body part or organ, they must continue to have preventative health screening of that organ per recommended guidelines. Additionally, TG patients who are currently on or have previously been on gender affirming hormone treatment are at increased risk for some medical conditions which may require more frequent preventative health screenings. It is important to obtain a thorough medication and surgical history to fully ascertain the individual's screening needs. *Table 4* provides and overview of preventive screening needs of TG patients.

TABLE 4. PREVENTATIVE HEALTH SCREENING FOR TG PATIENTS

Health Screening	Transgender Women	Transgender Men
Breast cancer	• Screen patients age >50 years based on established clinical guidance.	• Intact breasts: Routine screening as for natal females. • Postmastectomy: Yearly chest wall and axillary exams.
Cardiovascular Disease	• Recommended periodically in accordance with established guidance. Parameters should include weight, BMI, blood pressure, lipids, and blood sugar/A1C.	
Cervical cancer	• Vaginoplasty: no screening.	• Cervix intact: Routine screening as for natal females. • Absent cervix: No screening
Colon cancer	• Recommended in accordance with established guidance.	
Diabetes Mellitus	• Recommended periodically in accordance with established guidance. • If on estrogen: increased risk and frequency of screening may be increased.	• Recommended periodically in accordance with established guidance.
Hyperlipidemia	• Recommended periodically in accordance with established guidance. • If on estrogen: annual lipid screening.	• Recommended periodically in accordance with established guidance • If on testosterone: annual lipid screening
Osteoporosis	• Testes intact: Routine screening as for natal males. • Postorchiectomy: Screen all patients > 65 years. • Screen all patients age 50-65 years if off hormones for >5 years	• Screen all patients age >65 years • Screen patients age 50-65 if off hormones for >5 years
Prostate cancer	• Routine screening as for natal males.	• Not applicable
Testicular cancer	• Pre-orchiectomy with intact testes: Recommended periodically in accordance with established guidance.	• Not applicable
Refer to UpToDate *Primary Care of Transgender Individuals* and BOP *Clinical Guidance for Preventive Health Care* for additional information.		

14. MINIMALY INVASIVE AND NON-INVASIVE GENDER AFFIRMING TREATMENT MODALITIES

There are several minimally invasive and non-invasive gender-affirming treatment modalities available to TG patients such as voice and communication training, professional laser facial hair removal, and chondrolaryngoplasty (tracheal shaving). Lesser invasive or minor surgical procedures may be deemed medically necessary and considered on a case-by-case basis.

The purpose of these gender-affirming treatment modalities is to decrease or stabilize the gender dysphoria/incongruence experienced by the TG patient and improve the psychosocial functioning of the TG individual. The primary care treatment provider should use sub-specialty consultation requests in the electronic health record (EHR) to order these modalities. It is the responsibility of the medical provider to document the medical necessity, using accepted medical standards for gender-affirming treatment, for each of the requested lesser invasive and non-invasive interventions.

Requests for these treatment modalities (other than hormone treatment) such as voice and communication training, professional laser facial hair removal/electrolysis, will be reviewed in accordance with **Program Statement 6031 Patient Care**, section on Utilization Review; ***a subspecialty consult will be placed in BEMR and referred to the local Utilization Review committee for review. All procedures approved at the local URC meeting will require referral to the Regional Medical Director (RMD) for review and approval per PS 6031.***

Appendix 1. Transition Pathway for Transgender Patients lists the transition pathway for the affirmation treatment of the incarcerated TG individual from diagnosis to referral for major gender affirming surgery. These steps are not required to be fulfilled in chronological order before progressing to more invasive and non-reversible gender affirming treatment modalities but are an example of treatment modalities from least to most invasive.

VOICE AND COMMUNICATION TRAINING

Providers are encouraged to reach out to Regional Physical and Occupational Therapists, who can assist in finding appropriate resources. The American Speech-Language-Hearing Association (ASHA) has a provider directory for speech language pathologists who specialize in voice and communication therapy for transgender and gender diverse people.

FACIAL HAIR REMOVAL

Facial hair is often a source of distress and suffering for patients who identify as trans-female. Several noninvasive options are available to our incarcerated population. Patients can access the commissary to purchase extra razors, hygiene items such as hair removal creams and lotions, as well as foundation/coverage cremes/liquids to match the color of their skin; some of these products require special order purchases. Hair removal through waxing is a custody concern and is avoided in an incarcerated environment.

When commissary items fail to achieve desired results, and there is continued Gender Dysphoria, Health Services may provide over-the-counter laser hair removal devices as medically necessary. These are secured/maintained in Health Services and used by the patient under monitoring of staff.

Most laser hair removal devices marketed for at-home use are IPL (Intense Pulsed Light) devices. These devices cause a reduction in hair by emitting multiple wavelengths of light to the skin targeting melanin in the hair follicle, which then heats up the hair follicle causing it to weaken or be destroyed. IPL devices only work on hair that is in the growth phase and attached to the follicle therefore multiple treatments are often required. These devices work best on brown and black hair and typically do not provide results on white, grey, light blonde, or red hair. IPL devices work best on Fitzpatrick skin types I-IV which includes all skin tones except dark brown or black skin.

Another laser hair removal device marketed for at-home use is the diode laser. The diode laser works like the IPL devices, except instead of emitting multiple various wavelengths of light it emits a single wavelength of concentrated light. The diode devices are considered safer for all skin types as the IPL cannot be used on darker skin due to lower effectiveness and increased risk of skin burning. It is important to check what skin types the device can treat prior to obtaining the device.

Patients need to be educated on realistic expectations of these devices including: understanding that treatment often is not permanent; will require multiple treatments, often to the same areas; and different devices have varied effectiveness depending on skin and hair color, among other factors. Additionally, they are not without adverse reactions, sometimes causing skin irritation, pain, blistering or scarring. They should not be used on skin with large moles, birthmarks, or tattoos. All visible hair should be shaved in the area prior to use. Sun exposure, before and after treatments, should be avoided.

Prior to obtaining a laser hair removal device, institutions must check to see if the device is FDA cleared using the link: *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm.* Search by device name and look for the designation of "Substantially Equivalent (SESE)" to determine if FDA cleared. In addition, institutions will need to consider the options for cleaning between patient use with each product.

If these measures fail to remove the facial hair or are contraindicated (e.g., documented allergy or repeated infections) and patient has persistent unresolved Gender Dysphoria/incongruence, a referral consultation for professional laser facial hair removal or electrolysis may be submitted to the local Utilization Review Committee for consideration.

15. INVASIVE AND COMPLEX GENDER-CONFIRMING SURGERIES

➔ *Gender-Confirming surgery has also been referred to as sex reassignment surgery. It is important to note terminology changes often and the latter term is falling out of use.*

TG patients who have been compliant with all aspects of gender affirming care may desire further gender affirming treatment by requesting consideration for invasive and complex gender-confirmation surgery.

Gender confirming surgery may be medically necessary and is considered on a case-by-case basis. The BOP strives to provide community standard medical and surgical care within the confines its systems.

Surgical confirmation for trans individuals in BOP custody may be the final stage in their transition process. While many individuals may not require any surgery, for some it is medically necessary to complete more than a single procedure to alleviate their gender dysphoria/incongruence. See *Table 5* for different examples of surgical procedures.

TABLE 5. GENDER CONFIRMING PROCEDURES

Feminizing Surgical Procedures	
• Breast Augmentation	• Enlarging the breasts using breast implants
• Clitoroplasty	• Surgical creation of a clitoris
• Labiaplasty	• Creation or reshaping of the labia around the vagina
• Penectomy	• Removal of all or part of the penis
• Orchiectomy	• Removal of one or both testicles
Masculinizing Surgical Procedures	
• Bilateral Mastectomy	• Removal of both breasts
• Male Chest Contouring	• Contouring the chest into a masculine shape
• Hysterectomy	• Removal of the uterus
• Ovariectomy/Salpingo-oophorectomy	• Removal of ovaries/removal of ovaries and fallopian tubes
• Penile Prosthesis	• An erectile prosthetic device is placed to allow for an erection
• Phalloplasty	• Construction of a penis which may involve multiple surgeries
• Scrotoplasty	• Creation of a scrotum
• Metoidioplasty	• A surgical procedure that works with existing genital tissue to form a phallus, or new penis.
• Permanent Hair Removal	• When clinically required in preparation for bottom surgery

In accordance with ***Program Statement 5200.08 Transgender Offender Manual*****,** the TEC reviews all general administrative criteria for major gender affirming surgery and reviews additional correctional/custody considerations. The request for invasive and complex gender confirming surgery requires executive level administrative approval (by TEC), and approval from the Medical Director.

The **Clinical Director's (or designee's) role** at the referral institution is to support and treat the trans patient according to this guidance and document it accordingly. In general, clinical criteria for gender confirming consideration in the Bureau include the following:

- The patient has received ongoing gender affirming treatment by assigned medical and mental health providers, and there is persistent well-documented GD.
- There is clinical documentation of patient-centered discussions and documented ongoing follow-up regarding the specific therapeutic and surgical needs.
- The patient has been deemed capable to make fully informed decisions.
- Any significant medical and mental health conditions are reasonably well controlled.
- There have been 12 continuous months of hormone therapy as appropriate to the patient's individual goals (unless medically contraindicated).
  - Hormone therapy in trans-males is NOT a prerequisite for mastectomy and male chest contouring.
  - Hormone therapy in trans-females will maximize breast growth when continued for at least 2-3 years. Some surgeons will only perform the breast augmentation surgery after this period of time has elapsed. While this may be ideal, there will be times when Gender Dysphoria symptoms may warrant breast augmentation surgery after a minimum of one year of gender-affirming hormone treatment.
  - Patients should undergo masculinizing hormone therapy for at least 12-24 months prior to clitoral enlargement.

- There have been 12 continuous months of living in a gender role that is congruent with their gender identity. This experience provides ample opportunity for patients to experience and socially adjust to their desired gender role before undergoing irreversible surgery.
- Per ***Program Statement 5200.08 Transgender Offender Manual***,, the Warden submits a referral request to the TEC who will complete an administrative readiness review for gender-confirming surgery.
- When the TEC administratively approves a patient for surgical consideration, a referral is made to the Medical Director who remains the final authority in approving or disapproving a patient for gender confirming procedures. At the direction of the Medical Director, all pertinent clinical information will be reviewed by the Transgender Utilization Review Advisory Group to establish medical appropriateness for the procedure according to community standards.

Transgender Utilization Review Advisory Group Review

The Transgender Utilization Review Advisory Group is made up of members of the Transgender Clinical Care Team. Each utilization medical review meeting will require one pharmacist, one psychiatrist, a primary care physician and one social worker from the Transgender Clinical Care Team.

All clinical information in the surgical referral packet submitted by the patient's treatment providers is reviewed. The Transgender Utilization Review Advisory Group may need to interview the patient and/or contact members of the treatment team at the referring institution for additional clinical information (EKG, Pulmonary Function Testing, etc). A targeted utilization review is conducted to assure the proposed procedure(s) are medically needed and appropriate according to community standard prior to making their recommendation to the Medical Director. The Medical Director has the final clinical authority, according to BOP Policy, for approving/disapproving patients for referral for Gender Confirming Surgery.

Clinical Contents of the Gender Confirming Surgical Referral Packet

The **Surgical Referral Packet** should include the following items:

Mental Health Evaluation: the mental health professional (typically a Psychologist familiar with the patient) will document the patient's personal mental health and gender non-conformity history, progress, and suitability for surgery based on the stability of co-existing mental illness, and consolidation of one's identity. Recommended content of the mental health provider's referral for surgery include:

- The presenting general identifying characteristics.
- A list of all active mental health diagnoses.
- A review of history of suicidality, homicidality, history of violence, any psychiatric hospitalizations, and residential treatment for mental health or substance use.
- Any current and past substance use including nicotine.
- The duration of the mental health professional's relationship with the client, including the type of evaluation(s) and therapy or counseling to date.
- If and how long the patient has been living in the identified gender.
- An explanation that the criteria for surgery have been met, and a brief description of the clinical rationale for supporting the patient's request for surgery.

- Formal evaluation and documentation of capacity to give consent.
- Any issues regarding communication (e.g., English fluency, hearing impairments, an autism spectrum disorder, literacy level, learning differences, etc.)

MEDICAL EVALUATION: the objective of the medical evaluation of a pre-surgical candidate for gender-confirmation surgery is to establish medical suitability for the upcoming procedure. The medical evaluation will address both gender non-binary consolidation medical needs according to *WPATH*, as well as a general pre-surgical evaluation according to community standard. Recommended content for the medical evaluation for referral for surgery should include documentation on:

- Presence of persistent gender dysphoria/incongruence.
- Type of surgery patient is requesting.
- General statement about patient's ability to understand the irreversible aspects of the procedure.
- General patient discussion regarding risks for surgery which will be dependent on what type of surgery is being done. Some general risks to discuss with the patient include but are not limited to:
  - Significant pain.
  - Suboptimal appearance.
  - Risk related to general anesthesia to include death.
  - Excessive blood loss and need for transfusion.
  - Blood clots.
  - Damage to surrounding structures.
  - Nerve damage and loss of sensation.
  - Hematomas.
  - Infection or abscess potentially resulting in necrosis.
  - Excessive scarring.
  - Patient should also be informed that any detailed surgical technique information, risks of the procedure, and complication rates will be discussed with the surgeon, who is responsible for obtaining surgical consent.
- Documentation that the patient understands expected aftercare plan, what is to be expected during the healing process, and how the plan may change based on surgical results and recommendations from the surgeon.
- Patient History
  - History of present illness
    - Current medical and mental health status.
    - Medical and mental health conditions are reasonably well controlled.
  - Past medical history
  - Allergies

  - Medications
    - All active medications.
    - Dose and frequency.
    - Duration of hormone therapy (if applicable).
  - Review of systems
  - Family history
  - Social history
  - Surgical history
  - Sexual reproductive history and wishes
- Physical Exam (complete)
  - Including HEENT, cardiac, pulmonary, abdominal, extremities and neurologic
  - Special attention to signs of conditions that would be absolute/relative contraindications to surgery
- Laboratory Studies
  - Complete blood count with differential, comprehensive metabolic panel with liver function tests
  - Applicable hormone levels
- Pre-Surgical Work-Up- this may be at the preference of the surgeon and may include:
  - Recent EKG/Chest x-ray
  - Stress test
  - Nutritional assessment

PSYCHOSOCIAL EVALUATION: The social work psychosocial assessment for gender affirming surgery is utilized to gain a comprehensive understanding of the patient within their environment, both while incarcerated and upon release. It is completed by the social worker in the EHR. The assessment addresses the following areas:

- Family relationships, past and current
- Education, work/vocation, military history
- Religious/spiritual and/or cultural needs
- Financial resources
- Mental health, substance use, and medical history
- Sexual orientation and gender identity history
- Expectations or concerns regarding surgery
- Psychosocial functioning, support, and aftercare

16. TRANSITIONS OF CARE

Quality care and treatment includes planning for what will happen when a patient leaves the institution and BOP custody. Consultation with Transitional Care Team (TCT) should be pursued to assist with release planning efforts for transgender individuals, especially as it pertains to medical needs and gender affirming hormone therapy. The TCT can coordinate with relevant stakeholders and connect patients transitioning into the community with appropriate services and resources to ensure continuity of care. Aftercare planning for transgender individuals should include the following considerations:

NOTE: *If the institution is without a staff social worker, regional social workers are available to assist with aftercare planning.*

- A *Consent for Release of Medical Information* should be obtained from the inmate patient, in accordance with BOP policy, so that the inmate patient's treatment plan can be discussed with the community health care provider.
- An adequate supply of medications should be provided to the inmate prior to release or during community placement, in accordance with BOP policy.
- Patients transferring to Residential Re-entry Centers (RRC) or Home Confinement (HC) will be referred to BOP Health Systems Specialists (HSS) and Community Treatment Specialists (CTS) for continuity of care while in the RRC or on HC.
- If a patient is receiving gender affirming hormone therapy and is not transferring to RRC or HC, an aftercare plan should be established to ensure continuity of care.

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KEY TO ABBREVIATIONS

Below is a list of abbreviations used throughout this guidance.

➔ *See Section 2. Definitions for explanation of the terms marked with an asterisk (*).*

AEs	Adverse events
ARB	Angiotensin II receptor blocker
BMD	Bone mineral density
BMP	Basic metabolic panel, including glucose, calcium, sodium, potassium, CO2, chloride, blood urea nitrogen, and serum creatinine
CAD	Coronary artery disease
CBC	Complete blood count
CCARE	BOP Care Coordination and Reentry Team
CMA	Case Management Activity (codes)
CV	Cardiovascular
DM	Diabetes mellitus
FSH	Follicle-stimulating hormone
GD*	Gender dysphoria
GnRH	Gonadotropin-releasing hormone
hCG	Human chorionic gonadotropin
IM	Intramuscular
LFT	Liver function test
LH	Luteinizing hormone
N/V	Nausea and vomiting
PCOS	Polycystic ovarian syndrome
PREA	Prison Rape Elimination Act (see *Section 3*)
q	"Every" (example: q2wk = every 2 weeks)
SHBG	Sex hormone-binding globulin
SQ	Subcutaneous
TCCT*	BOP Transgender Clinical Care Team
TEC*	BOP Transgender Executive Council
TICC	Trauma-Informed Correctional Care in the BOP
TG*	Transgender
VTE	Venous thromboembolism

APPENDIX 1. TRANSITION PATHWAY FOR TRANSGENDER PATIENTS

1	**Patient self-identifies as TG or gender nonbinary to BOP staff member. Referral is made to a mental health professional or medical provider.**	
2	The mental health professional completes an assessment and documents gender non-conformity and/or gender dysphoria as indicated. (*Section 7*) Initiate gender-affirming live experiences within the prison system.	
3	Referral to medical provider for evaluation if patient has indicated an interest in initiating gender affirming hormone treatment (*Section 8*). Hormone treatment can be initiated prior to mental health evaluation, when/if patient presents to medical provider first and meets treatment criteria.	
4	Initiation of gender affirming hormone treatment after appropriate counseling completed on expected risks, outcomes, and complications. If needed, case can be discussed with BOP TCCT prior to initiation, though not required. Obtain informed consent (*Section 9*).	
5	***FEMINIZING THERAPY***	***MASCULINIZING THERAPY***
	Begin hormonal therapy with anti-androgen (spironolactone first, unless contraindicated) and estradiol Start low and titrate (no more than every few weeks) to appropriate level while using lowest effective dose. ➜ *See Section 11. Feminizing Hormone Therapy*	Begin hormonal therapy with testosterone Start low and titrate (no more than every few weeks) to appropriate level while using lowest effective dose. ➜ *See Section 12. Masculinizing Hormone Therapy*
	If treatment has reached maximum estradiol dose without desired effects after appropriate amount of time, consider adding another anti-androgen such as finasteride, a **GnRH** agonist, or medroxyprogesterone. Consult **BOP TCCT** if needed.	If still experiencing uterine bleeding after 6 months of high-dose testosterone therapy, consider adding medroxyprogesterone or a **GnRH** agonist to suppress menstruation. Consult **BOP TCCT** if needed.
6	After initiation and compliance with continuous gender affirming hormone treatment, a patient may request further gender affirmation by living in agender affirming institution. e.g., trans-female desires to live in a female institution/ trans-male desires to live in a male institution. The warden at the respective institution will request an administrative review by the TEC	
7	If approved by the TEC, the patient will be designated to the gender affirming institution (aka institution of the identified gender)	
8	Institutions that house transgender or gender non-conforming patients should develop a multidisciplinary team[1] who meet and discuss the patient's needs and progress	

(table continues on next page)

Transition Pathway for Transgender Patients (Cont.)	
9	After 12 months of living in the identified gender at the gender-affirming institution **or** original institution if the TG patient does not request transfer, compliance with continuous gender affirming hormone treatment and with documentation of persistent gender incongruence, the patient may benefit from lesser/non-invasive gender affirming treatment modalities or invasive/complex gender confirmation surgery[2] For all lesser/non-invasive gender affirming treatment modalities (ex. voice and communication training, professional laser facial hair removal) the individual provider will place the appropriate consult in the EHR and refer to the local Utilization Review Committee for review. Referral to the RMD will be required. For invasive/complex gender confirmation surgery- the warden at the respective institution will first request an administrative review by the TEC.
10	The TEC determines whether general administrative criteria for gender confirming surgery is met and refers the case to the Medical Director for a medical review. • The Medical Director will request review by the Transgender Utilization Review Advisory Group who will clinically review the surgical referral packet submitted by the Clinical Director. If the patient meets the clinical criteria for surgery, a memo, with all accompanying clinical supporting materials will be sent to the Medical Director, who is the final authority in approving a patient for referral to the gender confirming surgeon.
11	Gender confirming surgical evaluation will be completed by the contracted community surgeon who is responsible to meet with the patient to confirm readiness and medical suitability for complex surgery. Informed consent surrounding all aspects of the surgery to include risks, complication rates, and expected outcomes is the responsibility of the surgeon.

[1] Treatment team should consist of the Clinical Director (or designee), psychiatrist (as needed), Primary Care APP, psychologist, social worker, and pharmacist. Other representative members may include unit team, captain, chaplain (or patient representative), and associate warden. The patient may be invited to attend to clearly articulate and establish his/her clinical needs.
[2] Individuals will desire to progress to different stages of the stepwise approach. Only a subset of all gender non-conforming patients will pursue a surgical intervention.

APPENDIX 2. SUMMARY TABLES FOR FEMINIZING HORMONE THERAPY

➔ *See **Section 11** for more discussion on the medications used in Feminizing Hormone Therapy.*

➔ *These charts are not all-inclusive and are meant to summarize major considerations for medications. Refer to current drug interaction references, manufacturer information, and/or a pharmacist for additional information regarding drug dosing (to include renal and hepatic dosing), interactions, adverse effects, and contraindications.*

Table 1A: Anti-Androgen Drugs for Feminizing Hormone Therapy

★ GOAL LEVELS FOR MTF: SERUM ESTRADIOL 100-200 PG/ML AND SERUM TESTOSTERONE <50 NG/DL ★				
DRUG	**DOSE**	**MECHANISM OF ACTION**	**RISK CONSIDERATION /CONTRAINDICATIONS**	**NOTES**
SPIRONOLACTONE	• **Starting:** 25mg QD or BID • **Typical:** 100-300mg/day in 2 divided doses • **Max:** 200 mg BID	• Potassium-sparing antihypertensive that directly inhibits testosterone secretion and androgen binding to the androgen receptor	• Renal insufficiency • Potassium >5.5 mmol/L (use with caution if patient has comorbid condition or medications known to increase potassium)	
FINASTERIDE	• **Low:** 1 mg daily (generally used to treat androgenetic alopecia if needed and desired **after** individualized target level of androgen blockade is achieved) • **High:** 5 mg daily (generally used in those who cannot tolerate spironolactone or as an adjunct to spironolactone)	• 5α reductase inhibitor that blocks the conversion of testosterone to the more active 5α dihydrotestosterone (DHT)	• None pertinent	• Predicted to have little utility if the testosterone levels are suppressed and there is no substrate to generate DHT. • WPATH recommends against routine use in patients where testosterone and dihydrotestosterone levels have already been lowered with estrogen and an antiandrogen. Note, this includes for the use of androgenetic alopecia. • Use in combo with spironolactone for rare individuals not achieving desired effects. • May be used after orchiectomy if hirsutism or male pattern baldness are present. • When compared to placebo, 5-alpha-reductase inhibitors have been associated with an increase in the incidence of high-grade prostate cancers.
***APPENDIX 1, TABLE 1A, PAGE 1 OF 2** (see Key to Abbreviations in section preceding Appendices)*				

★ GOAL LEVELS FOR MTF: SERUM ESTRADIOL 100-200 PG/ML AND SERUM TESTOSTERONE <50 NG/DL ★				
DRUG	**DOSE**	**MECHANISM OF ACTION**	**RISK CONSIDERATION/ CONTRAINDICATIONS**	**NOTES**
GNRH AGONISTS: **GOSERELIN** **LEUPROLIDE**	• Goserelin: 3.6 mg SQ implant q4 weeks • Leuprolide: 3.75–7.5 mg SQ/IM monthly or 11.25mg SQ/IM q3 months ○ Lupron Depot® is administered IM ○ Eligard® is administered SQ	• Blocks the GnRH receptor, thus degreasing levels of FSH & LH resulting in highly effective gonadal blockade	• None pertinent	• Primary utilization is for patients who experience intolerable hyperkalemia, increased frequency of urination, and/or a reduction in blood pressure with spironolactone. • In cases of persistent elevations of testosterone despite maximized antiandrogen dosing, adherence must be thoroughly evaluated prior to consideration of GnRH Antagonist use. Directly observed therapy should be considered. If complete adherence is determined to exist, autonomous endogenous production (i.e., tumor) should be considered and appropriate evaluation should be conducted. • High cost should be considered in patients with proximal release dates. • Use can result in osteoporosis if doses of estrogen given concurrently are insufficient.
PROGESTIGENS: **MEDROXYPROGESTERONE**	• **Starting:** 2.5 mg daily • **Typical:** 5–10 mg daily • **Max:** 10 mg daily	• Inhibits secretions of pituitary gonadotropins	• Similar to estrogen. See ***CHART 1B*** below.	• No well-designed studies documenting efficacy. • Use in standard care generally lack formal recommendation for use. • If a patient is to be placed on a progestin, goals of use should be clearly documented and periodically evaluated. If goals are not achieved, medication should be discontinued. • Antidotal reports improved breast development, mood, and libido. However, evidence of benefit is unlikely to outweigh risk, which includes VTE
APPENDIX 1, TABLE 1A, PAGE 2 OF 2 *(see Key to Abbreviations in section preceding Appendices)*				

TABLE 1B: ESTROGEN FOR FEMINIZATION

★ GOAL LEVELS FOR MTF: SERUM ESTRADIOL <200 PG/ML AND SERUM TESTOSTERONE <50 NG/DL ★				
DRUG	**DOSE**	**MECHANISM OF ACTION**	**RISK CONSIDERATION/ CONTRAINDICATIONS**	**NOTES**
ESTRADIOL	• Typical: 2-6 mg daily • Occasionally higher doses are used as clinically indicated (literature recommends maximum does of 6-8mg depending on source) • If greater than 2 mg/day, recommend divided twice-daily dosing.	• Estrogens modulate the pituitary secretion of gonadotropins, LH, and FSH through a negative feedback system	**Absolute:** • Estrogen-dependent cancer **Precautions:** • History of thromboembolic disease (e.g., stoke, MI, DVT, PE) • Coronary artery disease • Hepatic dysfunction • Hyperlipidemia • Diabetes mellitus • Cigarette smoking • Migraine • Epilepsy • Retinal vascular thrombosis • Hypoparathyroidism • Porpyria • Diseases exacerbated by fluid retention	• Transdermal formulations are preferred for persons > 40 years old or those with risk factors for thromboembolic disease • Inform treatment team prior to surgery of hormone therapy. Individual risk assessment to determine adjustments to therapy perioperatively. • Individuals who enter the BOP on conjugated estrogen should be switched to a different form of estrogen due to inability to monitor estrogen levels with this preparation • IM injections cause greater peaks and troughs in estrogen levels making oral and transdermal preparations preferable
ESTRADIOL VALERATE IM (DELESTROGEN)	• **Typical:** 5-30 mg IM q2wk • *May divide dose into weekly injections for cyclical symptoms.*			
ESTRADIOL CYPIONATE IM (DEPO-ESTRADIOL)	• **Typical:** 2–10 mg IM q1wk			
ESTRADIOL PATCH (CLIMARA, ESTRADERM, ALORA, VIVELLE-DOT)	• **Typical:** 0.025 mg – 0.2 mg/day • *Max single patch dose available is 0.1 mg per 24 hours. More than one patch can be applied at a time* • *Frequency of patch change is brand/product dependent.*	*Same as above.*		

APPENDIX 1, TABLE 1B, PAGE 1 OF 1 *(see Key to Abbreviations in section preceding Appendices)*

APPENDIX 3. SUMMARY TABLE FOR MASCULINIZING HORMONE THERAPY

➔ ***See Section 12 for more discussion on the medications used in Masculinizing Hormone Therapy.***

➔ *These charts are not all-inclusive and are meant to summarize major considerations for medications. Refer to current drug interaction references, manufacturer information, and/or a pharmacist for additional information regarding drug dosing (to include renal and hepatic dosing), interactions, adverse effects, and contraindications.*

★ GOAL LEVELS FOR FTM: SERUM ESTRADIOL <50 PG/ML AND SERUM TESTOSTERONE 320–1000 NG/DL ★				
DRUG	**DOSE**	**MECHANISM OF ACTION**	**RISK CONSIDERATION/ CONTRAINDICATIONS**	**NOTES**
TESTOSTERONE CYPIONATE (in cottonseed oil) **TESTOSTERONE ENANTHATE (in sesame oil)**	• **Typical:** 50-100mg IM/SQ once weekly or 100-200mg IM every 2 weeks • **Max:** 200 mg q2wk or 100 mg/wk	• Maintains secondary sex characteristics in androgen-deficient patients	**Absolute:** • Pregnancy • Breast cancer (testosterone may have anti-proliferative effects on most, but not all, breast cancers) • Breastfeeding **Precautions:** • Erythrocytosis • Cardiac, hepatic, renal, or vascular disease with edema or risk of edema • Sleep apnea or high risk of sleep apnea due to obesity or chronic lung disease • Dyslipidemia • Migraines • Epilepsy • Depression, significant history of violent behavior	• Causes drop in blood glucose in DM individuals • May notice cyclic variation in mood with IM dosing Q 2–4 weeks. Use a lower, more frequent dose, or transdermal • Transdermal reaches same levels as IM, but in longer timeframe. • Menses typically stop in early months of treatment but may persist when using transdermals. • Testosterone is a DEA controlled substance. • For the first 3 to 9 months of treatment, total testosterone levels may be elevated with free testosterone levels remaining in the biological female range due to high sex hormone binding globulin levels in some biological women. • 15% of patients on testosterone will experience transient elevations in liver enzymes. If increase > 3x D/C and seek consultation. • Cypionate and enanthate formulations cannot be used interchangeably due to differences in duration of action.
TESTOSTERONE PATCH **Available strengths: 2 mg, 2.5 mg, 4 mg, 5 mg**	• **Typical:** 2.5-7.5 mg/day q PM • **Max:** 8 mg/day q PM			
TESTOSTERONE GEL (TESTIM 1%, ANDROGEL 1%)	• **Typical:**50-100mg/day			
TESTOSTERONE GEL (ANDROGEL 1.62%)	No published or anecdotal experience with these preparations			
TESTOSTERONE SOLUTION (AXIRON axillary solution)				
MEDROXYPROGESTERONE AND GNRH AGONISTS	Not routinely used. Refer to current drug references for dosing, mechanism of action, and contraindications/precautions.			• Use is recommended in patients who desire but have not yet begun testosterone therapy, or in conjunction with testosterone therapy for breakthrough bleeding
***APPENDIX 2, PAGE 1 OF 1** (see Key to Abbreviations in section preceding Appendices)*				

APPENDIX 4. MONITORING DURING FEMINIZING HORMONE THERAPY

Appropriate monitoring during gender-affirming hormone therapy is crucial to (1) ascertaining that target blood levels of hormones are being met and (2) assessing and maintaining the individual's health overall.

- **Clinical and laboratory monitoring** is appropriate every three months during the first year, and then as clinically indicated (typically once or twice yearly).
  - Monitor for development of feminine characteristics, for target blood levels, and for adverse effects of medication and other treatment.
- **Cardiovascular risk assessment** is recommended periodically for all patients treated with hormones in accordance with established guidelines and BOP guidance when available.
  - Specific parameters that should be monitored include weight and body mass index, blood pressure, lipids, and blood sugar and/or hemoglobin A1C levels, in accordance with established guidelines.
- **Serum ESTRADIOL and TESTOSTERONE levels** are obtained before starting those respective medications, and then every three months while on treatment.
  - **Target levels are <200 pg/ml for estradiol and <50 ng/dl for testosterone.** Higher levels of testosterone indicate inadequate suppression; higher levels of estradiol are associated with increased risks for thromboembolic disease, liver dysfunction, and development of hypertension.
- **Serum electrolytes, most importantly potassium, and renal function** are obtained prior to starting **SPIRONOLACTONE**, every three months during the first year of treatment, periodically thereafter, or more frequently with increases in dosage or as clinically indicated.
  - Dose adjustment or discontinuation of spironolactone is recommended for elevated potassium levels or serum creatinine >4 mg/dL.
- **Screening for colon and prostate cancer** is recommended in accordance with established guidelines and BOP guidance when available.
- **Breast cancer screening** guidelines for women are followed for transgender women treated with hormone therapy.
- **Screening for osteoporosis** with a DEXA scan may be appropriate in some cases. In addition, monitoring of hormone levels to ensure suppressed gonadotropin levels may serve as a surrogate marker to indicate adequate sex hormone levels in maintaining bone density in these patients.
  - In the absence of sufficient data to formulate evidence-based guidelines, it is considered appropriate to screen those who are at least five years post-gonadectomy, those who are 50 to 65 years old and have risk factors for osteoporosis, and all those who are 65 years or older.
  - Bone density measurements for transgender women are compared with standards for biological females.

- **Baseline and periodic monitoring of liver enzymes and prolactin levels** may be appropriate in those treated with **ESTRADIOL**, but there is insufficient data available to make a specific recommendation.

The following table below summarizes the monitoring schedule for individuals undergoing FEMINIZING hormone therapy.

➔ *See Key to Abbreviations in section preceding Appendices.*

LABORATORY MONITORING DURING FEMINIZING HORMONE THERAPY

Lab Test	Comments	Baseline	3 Mos[1]	6 Mos[1]	12 Mos[1]	Yearly	PRN
BMP	For individuals on spironolactone	X	X	X	X	X	
Lipids	As clinically indicated	X					X
A1C/Glucose	As clinically indicated	X					X
Estradiol	Range: generally, 100–200 pg/mL, but should not exceed 200 pg/ml	X	X	X	X	X	
Total Testosterone[2]	Range: < 50 ng/dL		X	X	X	X	
Prolactin	Only if symptoms of prolactinemia						X
LFTs	After baseline, optional if on estrogen, progesterone, or medroxyprogesterone	X				X	

[1] In the first year of therapy only

[2] Every 3 months in the first year then 1-2 times per year thereafter.

APPENDIX 5. MONITORING DURING MASCULINIZING HORMONE THERAPY

Appropriate monitoring during gender-affirming hormone therapy is crucial to (1) ascertaining that target blood levels of hormones are being met and (2) assessing and maintaining the individual's health overall.

➔ *A pregnancy test is obtained prior to starting treatment for all persons assigned as female at birth and have child-bearing potential.*

- **Clinical and laboratory monitoring** is appropriate every three months during the first year, and then as clinically indicated (typically once or twice yearly).
  - ➔ *Monitor for development of masculine characteristics, for target blood levels, and for adverse of effects of medication and other treatments.*
- Cardiovascular risk assessment is recommended periodically for all patients treated with hormones, in accordance with established guidelines and BOP guidance when available.
  - ▸ Specific parameters that should be monitored include weight and body mass index, blood pressure, lipids, and blood sugar and/or hemoglobin A1c levels.
- Serum testosterone levels are obtained before starting treatment with testosterone, and then every three months while on treatment.
  - ▸ Timing of the testosterone level is determined by the route of administration.
    - Testosterone enanthate/cypionate injections, testosterone levels should be obtained midway between injections. The target testosterone level is 400-700ng/dL.
    - Transdermal testosterone levels can be done any time after one week of therapy.
- Serum estradiol levels are obtained before starting hormone therapy, and then every three months while on treatment until estradiol levels are < 50 pg/ml and cessation of menses has been six months.
- A complete blood count (**CBC**) and liver panel are obtained prior to starting hormone therapy, every three months during the first year of treatment, once or twice yearly thereafter, or more frequently as clinically indicated.
  - ▸ Dose adjustment or discontinuation of testosterone is indicated if the hematocrit is > 54%.
- Screening for colon cancer is recommended in accordance with established guidelines and BOP guidance when available.
- Breast cancer screening guidelines for women are followed for **TG** individuals treated with hormone therapy and who have not had mastectomies.
- Cervical cancer screening is performed annually in those who are treated with hormone therapy and have cervical tissue (i.e., no hysterectomy).
- Screening for osteoporosis with a DEXA scan may be appropriate in some cases.
  - ▸ In the absence of sufficient data to formulate evidence-based guidelines, it is considered appropriate to assess bone mineral density prior to starting treatment in those with risk factors for osteoporosis, those who are at least five years status post-gonadectomy, and all those who are 60 to 65 years or older.

- Bone density measurements for transgender men are compared with standards for biological males.

The following table below summarizes the monitoring schedule for individuals undergoing hormone masculinizing therapy.

➔ *See Key to Abbreviations in section preceding Appendices.*

LABORATORY MONITORING OF MASCULINIZING HORMONE THERAPY

Lab Test	Comments	Baseline	3 Mos[1]	6 Mos[1]	12 Mos[1]	Yearly	PRN
CBC (Hgb & Hct)		X	X	X	X	X	
hCG (if child-bearing potential)		X					
Lipids	As clinically indicated	X					X
A1C/Glucose	As clinically indicated	X					X
LFTs		X		X	X	X	
Estradiol	Range: <50pg/mL		X				X
Total Testosterone[2]		X	X	X	X	X	X

[1] In the first year of therapy only

[2] If IM/SQ – check midway between injections (target level is 400-700ng/dL). Alternatively measure peak and trough levels to ensure levels remain in the normal male range. If patch – check after 1 week. Monitor levels every 3 months until levels are at goal.

APPENDIX 6. FEMINIZING GENDER-AFFIRMING HORMONE THERAPY – CONSENT AND COUNSELING FORM

FEMINIZING GENDER-AFFIRMING HORMONE THERAPY FOR TRANSGENDER PATIENTS

CONSENT AND COUNSELING FORM

INSTITUTION NAME: _____

PATIENT NAME: _____ **ID #:** _____

You want to take estrogen and other medications to feminize your body. Once you start these medications, some of them will need to be taken for the rest of your life to maintain their effects. Before using these medications, you need to know more about how they might affect you, including possible benefits, side effects, risks, and warning signs. We have listed them here for you. It's important that you understand all this information before you start. Please notify your health care provider should you have any questions.

WHAT ARE THE DIFFERENT MEDICATIONS THAT CAN HELP TO FEMINIZE YOU?

ESTROGEN is the female gender-affirming hormone. There are also medications—called **ANDROGEN ANTAGONISTS** (or **ANTI-ANDROGENS** or **ANDROGEN BLOCKERS)**—that stop the production of male hormones and can help you appear less like a man.

WARNING — WHO SHOULD NOT TAKE ESTROGEN?

It should NOT be used by anyone who has a current diagnosis of:

- An estrogen-dependent cancer
- Blood clots that could or did travel to the lungs

It should be used WITH CAUTION, and only after a full discussion of risks, by anyone who:

- Has a personal or strong family history of breast cancer or other cancers that grow faster when estrogens are present
- History of previous clots and currently not on blood thinners
- Has diabetes
- Has eye problems such as retinopathy
- Has heart disease, heart valve problems, or a tendency to have easily clotted blood
- Has hepatitis
- Has high cholesterol
- Has kidney or liver disease
- Has migraines or seizures
- Is obese
- Smokes cigarettes

Please review and **initial each statement** to show you understand the benefits, risks, and changes that may occur from taking these medications. At the end of the document, **indicate your preference regarding hormone therapy, then sign and date it.**

FEMINIZING EFFECTS OF ESTROGEN AND ANTI-ANDROGENS:

_____ I know that estrogen or anti-androgens—or both—may be prescribed to help me appear less like a man and more like a woman.

_____ I know that it can take several months to years for the effects to become noticeable. I know that no one can predict how fast—or how much—change will happen.

_____ I know that if I am taking estrogen, I will probably develop breasts.

- I know it can take several years for breasts to get to their full size.
- I know the breasts will remain, even if I stop taking estrogen.
- I know I should examine my breasts for irregularities as soon as they start growing. I should also have a clinician examine them every year.
- I know I might have a milky discharge from my nipples (galactorrhea). If I do, I know I should have it evaluated by my clinician because it could be caused by the estrogen or by other medications or medical conditions. I know that no one knows if taking estrogen increases the risk of breast cancer.

_____ I know that the following changes are usually not permanent—they are likely to go away if I stop taking the medicines:

- I know my body hair will become less noticeable and will grow more slowly, but it won't stop completely, even if I take the medicines for years.
- I know I will probably have less fat on my abdomen and more on my buttocks, hips, and thighs. It will be redistributed to a more female shape, changing from an "apple" shape to more of a "pear" shape.
- I know that if I already have male pattern baldness, it may slow down, but will probably not stop completely. It is also unlikely that hair that has been lost will grow back.
- I know I may lose muscle and strength in my upper body.
- I know my skin may become softer.

_____ I know that my body will make less testosterone. Upon release, this may affect my sex life in different ways and my future ability to cause a pregnancy:

- I know this treatment may (but is not assured to) make me permanently unable to make a woman pregnant.
- I know my sperm may no longer reach maturity. This could make me less able to cause a pregnancy. I also know I might never produce mature sperm again, but I know that it's also possible that my sperm could still mature. So, I know that I might get someone pregnant if we have vaginal intercourse, and we don't use birth control.
- I know this treatment may cause permanent infertility, and I will not be able to preserve or donate my sperm while incarcerated.

- I know my testicles may shrink down to half their size. Even so, I know that I will need regular checkups for them.
- I know it is likely that my penis won't be hard in the morning as often as it has been before. It is also likely that I will have fewer spontaneous erections.
- I know I may lose the ability to obtain an erection for intercourse.
- I know I may have less sex drive.
- I know that sex between inmates, or between inmates and staff, is not permitted within the BOP.

_____ I know that some parts of my body will not change much by using these medicines.

- I know the hair of my beard and moustache may grow more slowly than before. It may become less noticeable, but it will not go away.
- I know the pitch of my voice will not rise, and my speech patterns will not become more like a woman's.
- I know my Adam's apple will not shrink.
- Although these medicines can't make these changes happen, there are other treatments that may be helpful.

RISKS OF TAKING FEMINIZING MEDICATIONS (ESTROGEN AND ANTI-ANDROGENS):

_____ I know that the side effects and safety of these medicines are not completely known. There may be long-term risks that are not yet known.

_____ I know that I should not take more medicine than I am prescribed. I know it increases health risks. I know that taking more than I am prescribed won't make changes happen more quickly or more significantly. I know my body can convert extra estrogen into testosterone which can slow down or stop my appearing more womanly.

_____ I know these medicines may damage the liver and may lead to liver disease. I know I should be checked for possible liver damage as long as I take them.

_____ I know these medicines cause changes that other people will notice. Some transgender people have experienced harassment, discrimination, and violence because of this. Others have lost the support of loved ones. I know I can reach out to psychology services to help me find support resources. I also know that the BOP does not tolerate harassment, discrimination, and violence in any circumstances. If I feel I am the recipient of any of these actions, I will notify a BOP staff member.

RISKS OF TAKING ESTROGEN:

_____ I know that taking estrogen increases the risk of blood clots that can result in:

- Chronic problems with veins in the legs
- Heart attack
- Pulmonary embolism (blood clot to the lungs), which may cause permanent lung damage or death
- Stroke, which may cause permanent brain damage or death

_____ I know that the risk of blood clots is much worse if I smoke cigarettes, especially if I am over 40. I know the danger is so high that I should stop smoking completely if I start taking estrogen and that I should not start to smoke again when I am released from a BOP institution.

_____ I know that taking estrogen can increase the deposits of fat around my internal organs. This can increase my risk for diabetes and heart disease.

_____ I know that taking estrogen can raise my blood pressure. I know that if my blood pressure goes up, my clinician can work with me to try to control it with diet, lifestyle changes, and/or medication.

_____ I know that taking estrogen increases my risk of getting gallstones. I know that I should talk with my clinician if I get severe or long-lasting pain in my abdomen.

_____ I know that estrogen can cause nausea and vomiting. I know that I should talk with my clinician if I have long-lasting nausea or vomiting.

_____ I know that estrogen can cause headaches or migraines. I know I should talk with my clinician if I have headaches or migraines often, or if the pain is unusually severe.

_____ I know that it is not yet known if taking estrogen increases the risk of prolactinomas. These are non-cancerous tumors of the pituitary gland. I know they are not usually life-threatening, but they can damage vision and cause headaches. I know this possibility needs to be checked periodically by a clinician for at least three years after I start taking estrogen.

_____ I know that I am more likely to have dangerous side effects if:

- I smoke.
- I am overweight.
- I am over 40 years old.
- I have a history of blood clots.
- I have a history of high blood pressure.
- My family has a history of breast cancer.

RISKS OF TAKING ANDROGEN ANTAGONISTS:

_____ I know that spironolactone affects the balance of water and salts in the kidneys, which may:

- Increase the amount of urine I produce, making it necessary to urinate more frequently.
- Increase thirst.
- Reduce blood pressure.
- Cause (although rarely) high levels of potassium in the blood, possibly leading to changes in heart rhythms that may be life-threatening.

_____ I know that some androgen antagonists make it more difficult to evaluate test results for cancer of the prostate. I know that if I am over 50, I should have my prostate evaluated every year with a prostate-specific antigen test, as applicable.

PREVENTION OF MEDICAL COMPLICATIONS:

_____ I agree to take feminizing medications as prescribed, and I agree to tell my clinician if I have any problems or if I am unhappy with the treatment.

_____ I know that the dose and type of medication that is prescribed for me may not be the same as for someone else.

_____ I know that I need periodic physical exams and blood tests to check for any side effects.

_____ I know that feminization medications can interact with other drugs and medicines—including alcohol, diet supplements, herbs, other hormones, and street drugs—causing complications. I know that I need to prevent complications because they can be life-threatening. That's why I need to be honest with my clinician about whatever else I take or use. I also know that this will not interfere with my getting medical care; I will continue to get medical care here no matter what information I share about what I take.

_____ I know that it can be risky for anyone with certain conditions to take feminizing medicines. I agree to be evaluated if my clinician thinks I may have such a condition. Then, we will decide if it's a good idea for me to start or continue using these medications.

_____ I know that there may be a risk for blood clots after surgery, especially if I will not be mobile for an extended period. I will need to talk with the surgeon and my doctor to decide if I need to stop taking estrogen before and/or after the surgery or immobilizing event.

_____ I know that using these medicines to appear more womanly is an "off-label" use. I know that this means that using these medicines for this purpose is not approved by the Food and Drug Administration (FDA). I know that the medicine and dose that is recommended for me is based on the judgment and experience of the clinician.

_____ I know that I can choose to stop taking these medicines at any time. I know that if I decide to do that, I should do it with the help of my clinician. This will help me make sure there are no negative reactions. I also know that my clinician may suggest that I cut the dose or stop taking it altogether if certain conditions develop. This may happen if the side effects are severe or if there are health risks that cannot be controlled.

MY SIGNATURE BELOW CONFIRMS THAT:

- My clinician has talked with me about:
  - The benefits and risks of taking feminizing medication.
  - The possible or likely consequences of hormone therapy.
  - Potential alternative treatments.

_____
_____
_____
_____
_____

- I understand the risks that may be involved.
- I know that the information in this form includes the known effects and risks. I also know that there may be unknown long-term effects or risks.
- I have had enough opportunity to discuss treatment options with my clinician.
- All of my questions have been answered to my satisfaction.
- I believe I know enough to take, refuse, or postpone therapy with feminizing medications.
- I am 18 years old or older.

BASED ON ALL THIS INFORMATION:

_____ I understand the risks, and consent to taking estrogen.

_____ I understand the risks, and decided I do not consent to taking estrogen

_____ I understand the risks, and consent to taking androgen antagonists (e.g., spironolactone).

_____ I understand the risks, and decided I do not consent to taking androgen antagonists (e.g., spironolactone).

_____ _____
Patient's Signature *Date*

_____ _____
Prescribing Physician's Signature *Date*

Your health is important to us. If you have any questions or concerns, please come to sick call and an appointment with your provider will be made.

APPENDIX 7. MASCULINIZING GENDER-AFFIRMING HORMONE THERAPY – CONSENT AND COUNSELING FORM

MASCULINIZING GENDER-AFFIRMING HORMONE THERAPY FOR TRANSGENDER PATIENTS

CONSENT AND COUNSELING FORM

INSTITUTION NAME: _____

PATIENT NAME: _____ **ID #:** _____

You have expressed a desire to take testosterone to masculinize your body. Before beginning treatment, there are several details about treatment that you need to be familiar with, including the possible advantages, disadvantages, risks, warnings, and alternatives. These topics are covered below. It is important that you understand all this information before initiating treatment. Please notify your health care provider should you have any questions.

WHAT IS TESTOSTERONE?

Testosterone is the hormone responsible for male features. It builds muscle, causes the development of facial hair, and is responsible for the deepening of a person's voice during puberty. Testosterone also may increase sex-drive.

HOW IS TESTOSTERONE TAKEN?

Testosterone is usually injected every one to four weeks. It is not used as a pill because the body may not absorb it properly, and it can cause liver problems. Some people use skin creams and patches, but these are not used in the correctional environment.

The doses used for injections differ from product to product, and from patient to patient. Doses may range from 100 mg to 400 mg. The injections are administered into a large muscle to slow the release of the hormone. There can be unwanted swings in hormone levels. This can be controlled by changing how often the dose is given, how much of a dose is given, or by changing formulations.

WARNING — WHO SHOULD NOT TAKE TESTOSTERONE?

Testosterone should ***not*** be used by anyone who is pregnant or has uncontrolled coronary artery disease.

It should be used ***with caution and only after a full discussion of risks*** by anyone who has: acne, family history of heart disease or breast cancer, blood clot history, high levels of cholesterol, liver disease, or high red-blood-cell count. Caution should also be used in obese patients and persons who smoke.

MONITORING:

Periodic blood tests to check on the effects of the hormone will be required for treatment. Routine breast exams and pelvic exams with pap tests should be continued, when applicable.

BENEFITS AND RISKS OF TESTOSTERONE TREATMENT:

Benefits	Risks

• Appearing more like a man:
  • Larger clitoris*
  • Coarser skin
  • Deeper voice*
  • Increased body hair*
  • Increased facial hair*
  • Increased muscle mass
  • Increased strength
  • Elimination of menstrual periods
• Increased physical energy
• Protection against bone thinning (osteoporosis)
 	
**These are permanent changes.*
	• Acne (may permanently scar)
	• Blood clots (thrombophlebitis)
	• Emotional changes
	• Headache
	• High blood pressure (hypertension)
	• Increased red-blood-cell count
	• Infertility
	• Inflamed liver
	• Interaction with drugs for diabetes and blood thinning, e.g., Coumadin and Warfarin
	• Male pattern baldness
	• Increased abdominal fat
	• Increased risk of heart disease
	• Swelling of hands, feet, and legs
	• Weight gain

Please review and **initial each statement** to show that you understand the benefits, risks, and changes that may occur from taking these medications. At the end of the document, **indicate your preference regarding hormone therapy, then sign and date it.**

MASCULINIZING EFFECTS OF TESTOSTERONE:

_____ I know that testosterone may be prescribed to make me appear less like a woman and more like a man.

_____ I know that it can take several months or longer for the effects to become noticeable.

_____ I know that no one can predict how fast or how much change will take place.

_____ ***I know that the changes may not be complete for two to five years after starting testosterone.***

_____ ***I know the following changes are likely to be permanent, even if I stop taking testosterone:***

- Bigger clitoris — typically about half an inch to a little more than an inch
- Deeper voice
- Growth of facial hair (moustache and beard)
- Hair loss at the temples and crown of the head and the possibility of becoming completely bald
- More, thicker, and coarser hairs on abdomen, arms, back, chest, and legs

_____ ***I know that the following changes are usually NOT permanent and will likely go away if I stop taking testosterone:***

- Acne (however, acne scars will be permanent)
- Elimination of menstrual periods (typically stop one to six months after starting testosterone)
- Increased abdominal fat (redistribution of fat to a more masculine shape)
- Decreased fat on buttocks, hips, and thighs
- More muscle mass and strength

- Vaginal dryness

_____ I know that the effects of testosterone on fertility are unknown and may cause permanent infertility. I have been told that I may or may not be able to get pregnant even if I stop taking testosterone. I know I might still get pregnant even after testosterone stops my menstrual periods. I know I cannot take testosterone if I am pregnant. By continuing treatment, I accept that I may never be able to biologically parent a child. I know this treatment may cause permanent infertility, and I will not be able to preserve or donate my eggs while incarcerated

_____ I know that some aspects of my body will not be changed:

- Losing some fat may make my breasts appear slightly smaller, but they will not shrink very much.
- Although my voice may deepen, other aspects of the way I speak will not change.

_____ I know that there are other treatments that may be helpful to make my breasts smaller or my speech manlier. If I have concerns, I can discuss treatment options with my clinician.

RISKS OF TESTOSTERONE:

_____ I know that the medical effects and safety of testosterone are not completely known. There may be long-term risks that are not yet known.

_____ I know not to take more testosterone than prescribed. I know this would be a risk to my health. I know that taking more testosterone than I am prescribed will not make changes happen more quickly or more significantly. I know that my body can convert extra testosterone into estrogen, which can slow down or reverse the progress of my transition.

_____ I know that testosterone can cause changes that increase my risk of heart disease. I know these changes include:

- Less good cholesterol (HDL), which is needed to protect against heart disease, and more bad cholesterol (LDL), which may increase the risk of heart disease
- Higher blood pressure
- Increased deposits of fat around my internal organs

_____ I know that my risk of heart disease is higher if people in my family have had heart disease, if I am overweight, or if I smoke.

_____ I know that I should have periodic heart-health checkups for as long as I take testosterone. I know I must watch my weight and cholesterol levels and have them checked by my clinician.

_____ I know that testosterone can damage the liver and possibly lead to liver disease. I know I should be checked periodically for possible liver damage for as long as I take testosterone.

_____ I know that testosterone can increase my red blood cell count and hemoglobin. I know the increase is usually only to the level that is normal for a man. I know normal levels would have no health risks; however, higher increases can cause problems that can be life-threatening. These problems include stroke and heart attack. As such, I know I need to have periodic blood checks for as long as I take testosterone.

_____ I know that taking testosterone can increase my risk for diabetes. It may decrease my body's response to insulin, cause weight gain, and increase deposits of fat around my internal organs. I know I should have periodic checks of my blood glucose for as long as I take testosterone.

_____ I know that my body can turn testosterone into estrogen. I know that no one knows if this could increase the risk of cancers of the breast, ovaries, or uterus.

_____ I know that taking testosterone can thin the tissue of my cervix and the walls of my vagina. This can lead to tears or abrasions during vaginal intercourse. I know it does not matter if my partner is a woman or a man. This raises my risk of getting a sexually transmitted infection, including HIV. I know I should speak frankly with my provider regarding the best ways to prevent and check for infections.

_____ I am aware that sex between inmates, or between inmates and staff, is not permitted.

_____ I know that testosterone can give me headaches or migraines. I know it is best to talk with my clinician if I get them frequently or if the pain is unusually severe.

_____ I know that testosterone can cause emotional changes. For example, I could become more irritable, frustrated, or angry. I know my provider can help me find resources to explore and cope with these changes.

_____ I know that testosterone causes changes that other people will notice. Some transgender people have experienced harassment, discrimination, and violence because of this. Others have lost the support of loved ones. I know I can reach out to psychology services to help me find support resources. I also know that in the BOP, harassment, discrimination, and violence are not tolerated under any circumstances. If I feel I am the recipient of any of these actions, I will notify a BOP staff member.

PREVENTION OF MEDICAL COMPLICATIONS:

_____ I agree to take testosterone as prescribed, and I agree to tell my clinician if I have any problems or am unhappy with the treatment.

_____ I know that the dose and type of medication prescribed for me may not be the same as it is for someone else.

_____ I know that I need periodic physical exams and blood tests to check for any side effects.

_____ I know that testosterone can interact with other drugs and medicines, including alcohol, diet supplements, herbs, other hormones, and street drugs. This kind of interaction can cause complications. I know that I need to prevent complications because they can be life-threatening. I need to be honest with my clinician about other items I am taking. I also know that this will not interfere with my getting medical care; I will continue to get medical care here no matter what information I share about what I take.

_____ I know that it can be risky for anyone with certain conditions to take testosterone. I agree to be evaluated if my clinician thinks I may have one of these conditions. Then, we will decide if it is a good idea to start or continue using testosterone.

_____ I know that using testosterone to appear more masculine is an "off-label" use. I know this means it is not approved by the Food and Drug Administration (FDA) for this purpose. I know the medicine and dose recommended for me is based on the judgment and experience of the clinician.

_____ I know that I can choose to stop taking testosterone at any time. I know if I decide to stop, I should discontinue with the help of my clinician to ensure there are no negative reactions. I know my clinician may suggest I cut the dose or stop taking it altogether if certain medical conditions develop. This may happen if the side effects are severe or if there are health risks that cannot be controlled.

MY SIGNATURE BELOW CONFIRMS THAT:

- My clinician has talked with me about:
  - The benefits and risks of taking testosterone.
  - The possible or likely consequences of hormone therapy.
  - Potential alternative treatments.
  - _____
    _____
    _____
    _____
- I understand the risks that may be involved.
- I know that the information in this form includes the known effects and risks. I also know that there may be unknown long-term effects or risks.
- I have had enough opportunity to discuss treatment options with my clinician.
- All of my questions have been answered to my satisfaction.
- I believe I know enough to take, refuse, or postpone testosterone therapy.
- I am 18 years old or older.

BASED ON ALL THIS INFORMATION:

_____ I understand the risks, and consent to taking testosterone.

_____ I understand the risks, and decided I do not consent to taking testosterone at this time.

_____ _____
Patient's Signature *Date*

_____ _____
Prescribing Physician's Signature *Date*

Your health is important to us. If you have any questions or concerns, please come to sick call and an appointment with your provider will be made.