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| new logo small for | Protocol for the provision of LGBTQ Affirming Care |

**Introduction**

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**Credits and Acknowledgement**

The following document contains an original protocol for the provision of best practices in providing culturally competent care to the LGBTQ population at IFH. A second protocol within this document (Hormone Therapy) is a direct adaption of the existing protocols developed and in use by Callen Lorde Community Health Center (New York, NY), and was originally obtained via permission from the Department of Transgender Protocol Requests (212-271-7200). This document is not intended for use beyond the permissions obtained by the Institute for Family Health. Individuals and entities should contact Callen Lorde directly for guidance regarding permission and use, although it is notable that this organization has recently made their version of this protocol public domain.

**Internal Review and Adaptation**

This protocol was reviewed by a number of medical and mental health providers at the **Institute for Family Health** in considering its adaptation to our patient population:

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**Disclaimers**

This protocol was developed by **Callen Lorde** based on the clinical experience of medical and mental health providers engaged in service delivery with the transgender population, who note it is not the product of scientific studies or clinical trials. Scholarly literature to date has been reviewed and has helped to inform this protocol, but the original document notes that there is no medication currently approved by the FDA specifically for the provision of cross-gender hormone therapy. As such, treatment is offered and implemented based upon voluntary initiation and is based upon consent by the patient and upon the clinical judgment of the provider.

**A Note on Age and Informed Consent**

These protocols were written for use in patients **18 years of age or older.** At the Institute for Family Health, we have decided to place the lower limit for treatment using hormone therapy at age 18. While there is emerging evidence of the benefits of suppression of puberty, this protocol does not account for the biopsychosocial needs unique to pubescent and prepubescent patients, nor does it address the complex nature of obtaining informed consent for minors. This will continue to be explored in future adaptations of this work within our organization.

**LGBTQ Health Task Force Vision and Mission Statement**

The mission of the Institute for Family Health’s LGBTQ Health Task Force is to expand LGBTQ cultural consciousness and competence among Institute employees, to create a welcoming and inclusive work culture, to develop supportive programming for LGBTQ patients, and to improve access to high quality, patient-centered primary care targeted to the needs of medically underserved LGBTQ individuals and families. Our vision is to enhance the scope of practice for our providers so that there is “no wrong door” for patients seeking to integrate their gender-related health care needs with primary care and behavioral health care, and ultimately to reduce health disparities that have historically put this population at particular risk for poor outcomes.

**SECTION I: LGBTQ Inclusive Health Care Policy**

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| new logo small for | **Subject:** Provision of LGBTQ Inclusive Healthcare at IFH |
| **Department(s):** Agency Wide (Administrative, Clinical, and Psychosocial) |
| **Prepared by:** The LGBTQ Health Task Force (Cynthia Kim, LCSW-R, Ken Myers, LMSW, Stephanie Richers, LMSW, Courtney Glashow, LMSW, Deena Levine, LMSW, Matt Yetsko, LMSW, Robert Schiller, MD, Elisa Wallman Jacques, LMSW, Insung Min, MD, Emily Hackenburg, NP) |
| **Approved by:** CDG and AMG |

**Introduction:** The Institute for Family Health (IFH) is committed to creating a welcoming and inclusive work culture, to develop supportive programming for LGBTQ patients, and to improve access to high quality, patient-centered primary care and behavioral health care targeted to the needs of medically underserved LGBTQ individuals and families. Our vision is to enhance the scope of practice for our providers so that there is “no wrong door” for LGBTQ identified patients seeking medical and behavioral health care, and ultimately to reduce health disparities that have historically put this population at particular risk for poor outcomes.

**Population:** The Institute for Family Health will provide the full complement of care to individuals across the lifespan. Hormone therapy and other gender transition related services are currently available for individuals ages 18 and older who are able to independently consent to treatment. The task force will continue to work toward developing quality programming to meet the needs of younger adults and adolescents who are interested in gender transition services.

**Purpose and Scope:** To provide guidelines for quality care for this population, provision of hormone treatment, and best practices for working with individuals who are seeking gender confirmation surgery at all sites, services, and programs owned and operated by IFH.

**Policy:** All personnel are expected to abide by the guidelines set forth in this document as well as within any related protocols for best practices. IFH will not deny treatment to any patient based on insurance status or ability to pay consistent with federal guidelines for Federally Qualified Health Centers (FQHC). All IFH providers and staff are expected to provide culturally conscious and competent care to this population in general. All providers will be trained to provide coverage for transgender care but participation in provision of hormone treatment is voluntary. Grievances or patient complaints related to quality of care for this population may be directed to the LGBTQ Health Task Force chair Ken Myers, LMSW for review and action by the committee.

**Patient Referrals:** Patients may self-refer from the community or be referred by a provider within IFH. Case management services, mental health, specialty care services can be provided if needed, and patients needing a more comprehensive level of care or a type of care that is beyond the scope of practice for IFH providers will be offered appropriate community referrals. Patients who are uninsured or underinsured will be referred for public insurance or sliding fee programs consistent with the established IFH policies surrounding Sliding Fee Discounts and Care for the Uninsured. A list of available and inclusive community resources will be maintained by the LGBTQ Health Task Force for each region.

**Staff and Provider Training/Requirements:** Whereas all staff and providers are expected to provide quality, LGBTQ-affirming health care to this population:

* Participation in gender transition related ***training*** is required in order to provide adequate coverage for established patients
* Participation in providing gender transition services ***is not*** required but is strongly encouraged
* Staff and providers will complete a credentialing process that involves training and assessment for competency, providers will have this credential added to their delineation of privileges
* Specific competencies are provided for in the Association for Lesbian, Gay, Bisexual, and Transgender Issues in Counseling Competencies document attached to this protocol (Appendix E)
* For both psychosocial and medical assessment and care, providers must be a licensed in NYS or license-eligible (e.g., LCSW, PH.D., MD, DO)

**Psychosocial Services Involvement:** A biopsychosocial assessment will be completed for each patient interested in gender transition services so that a thorough and accurate history can be established, medical care can be facilitated, and any necessary ancillary services can be coordinated within a team-based approach to providing holistic care.

**Program Review and Quality Improvement:** Quality assurance will be measured through a number of domains and will be reported to the Vice President for Quality Assurance on an annual basis

* Patient satisfaction as measured by percentage of (and outcomes from any) patient complaints or QA concerns
* Retention rates (% of patients initiating and continuing transgender health or behavioral health care at IFH)
* Chart reviews to establish fidelity to the model and standards of care, to be reviewed by the LGBTQ Health Task Force quarterly
* Maintenance of credentialing and appointment via submission of 2 or more CEU/CME hours per year

**Compliance:** The LGBTQ Task Force will review compliance with Institute policy and procedure as part of the annual work plan review process

**Confidentiality:** Staff and providers must comply with all applicable laws and regulations regarding the privacy and confidentiality of any medical records in general and of information pertaining to this population

**SECTION II: Guide to Using the Hormone Protocol**

**Specific Timing and Implementation of the Interventions**

Implementation of this protocol will vary as needed based upon the unique culture of each practice setting within IFH where it is adopted for use. The timing of each intervention step was originally written based on the regular functions of a particular clinic setting and is offered as a general set of guidelines for use in adapting the protocol and workflows. In general, the following are noted as key concepts for adaptive implementation:

* When starting a new medication, start at half-dose (prescribe enough for one month only)
* Reassess the patient after one month (bloodwork, history, psychosocial factors, and physical evaluation) before increasing the medication to full dose
* Reassess the patient one month later at full dose
* Reassess the patient three months later, six months later, then every 6-12 months
* Maintain a harm reduction approach to ensure patient safety

**Please note that there are several components to this portion of the document:**

* Table of contents
* Clinical visit protocol
* Hormone dosing tables by visit
* Special considerations
* Managing comorbidities
* Managing lab abnormalities
* References
* Sample consent forms

**Hormone Therapy Protocol**

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**Clinical Visit Protocol**

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| **Visit 1** | **Biopsychosocial Assessment** |
| **Provider** | Mental Health Provider |
| **Goals of the Session** | To assess for mental health presenting problems or other presenting problems that may complicate treatment  To assess patient’s need for case management services if there are barriers to accessing care  To connect patient with appropriate case management, behavioral health, and mental health services as needed  To assess patient ability to provide informed consent to initiate Cross-Gender Hormone Therapy |
| **Activities** | |
| **Complete Psychosocial Intake** | Cultural Formulation Interview (if appropriate)  History and treatment history of any mental health problems and/or psychiatric diagnoses , medical problems  Assessment of current symptoms (include PHQ9 and GAD7) and mental status  Assess social history and history of transgender identity |
| **Discuss Possible Diagnoses** | Gender Dysphoria (302.6)  Unspecified Endocrine Disorder (259.9/E34.9) |
| **Initiate discussion of informed consent to initiate Cross-Gender Hormone Therapy** | Assess that the patient’s goals and understanding of Cross-Gender Hormone Therapy match the general nature and purpose of Cross-Gender Hormone Therapy |
| Assess patient’s understanding of the physical, mental health, and social benefits and risks of Cross-Gender Hormone Therapy |
| When applicable discuss alternatives to Cross-Gender Hormone Therapy |
| **Arrange Follow-Up Visits** | Primary care visit (scan consents and send report to pcp) w/in 1 week  Behavioral health/mental health or case management (2 weeks or as needed)  Link patient with local LGBTQ community center |

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| **Visit 2** | **Initial Medical Intake** |
| **Provider** | Medical Provider |
| **Goals of the Session** | Connect or engage patient in primary care  Introduce patient to transgender health care program  Obtain medical history  Begin hormone therapy assessment |
| **Activities** | |
| **Introduction** | Introduce patient to the Institute for Family Health if they are not already established as a medical patient, discuss transgender health care program |
| **Begin Hormone Therapy Assessment** | Discuss importance of connection with social support and community support over the course of treatment |
| Connect with social work or case management if resource linkages are needed |
| Discuss hormones, risks and benefits, elicit patient expectations |
| **Obtain Medical History** (Especially Conditions that can be exacerbated by hormone therapy) and **Family Medical History (including but not limited to the following)** | Cancer (i.e., breast, colon, ovarian, prostate, uterine)  Coronary Artery Disease/Heart Disease  Deep Vein Thrombosis/Pulmonary Embolus/Embolic Stroke  Diabetes  Erythrocytosis  Hypertension  Liver disease  Pituitary adenoma |
| **Assess and Update Health Care Maintenance** | Tuberculosis screening (PPD status)  Breast/chest Self-Exam  Testicular Self-Exam  Pelvic exam  HIV status and risk assessment  Complete physical exam |
| **Allergies and Immunizations** | Hepatitis A  Hepatitis B  Measles/Mumps/Rubella (MMR)  Tetanus/diphtheria (Td/Tdap)  Influenza  Pneumococcus  Human Papillomavirus (HPV) |

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| **Visit 2 Activities Continued** | **Initial Medical Intake** |
| **Document Current Medication** | Prescribed  Herbal  Over the counter  Street  Supplements  Prior hormone use |
| **Review Mental Health History** | Address engagement in any needed services or pre-existing services |
| **Review Social History** | Alcohol and Substance Use (including tobacco, street hormone use)  Educational and Employment history  Domestic Violence  Living Situation  Sexual History (including gender identity history and any previous transgender care)  Social Supports  Silicone Use |
| **Order Bloodwork/Labs** | Complete Blood Count  Comprehensive Metabolic Panel (electrolytes, liver enzymes, lipids)  Hepatitis A, B and C panel  STD Screening and Testing |
| ***Note:*** *Some guidelines recommend checking estradiol and testosterone levels at baseline and throughout the monitoring of estrogen therapy. A clinical use for testing baseline routine hormone levels that justifies the expense has not been demonstrated.* | |
| **Obtain Consent for Release of Information from Previous Providers if Applicable** | |
| **Schedule Follow Up Visits** | Hormone Counseling & Education Session (1 week)  Behavioral Health or case management if Needed |

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| **Visit 3** | **Hormone Counseling & Education Session** |
| **Provider** | Medical Provider or Nursing Provider |
| **Goals of the Session** | To review patient ability to provide informed consent to initiate Cross-Gender Hormone Therapy  To assess management of mental health complaints that might be adversely affected by Cross-Gender Hormone Therapy  To assess additional biopsychosocial needs of patient and offer related referrals/resources as indicated and/or requested |
| **Activities** | |
| **Review lab results and previous treatment records, if any** | Offer and provide treatment if necessary, give any needed vaccines, assess progress with any other services or treatment (e.g., mental health) |
| **Introduce Purpose of Hormone Counseling & Education Session** | Counsel about the known risks and benefits of exogenous hormone therapy and confirm patient can provide informed consent to Cross-Gender Hormone Therapy |
|  | Communicate assessment and findings to the medical provider who will be prescribing Cross-Gender Hormone Therapy |
| **Review informed consent to Cross-Gender Hormone Therapy** | Assess that the patient’s goals and understanding of Cross-Gender Hormone Therapy match the general nature and purpose of Cross-Gender Hormone Therapy |
|  | Assess patient’s understanding of the physical, mental health, and social benefits and risks of Cross-Gender Hormone Therapy. Discuss alternatives to CGHT if appropriate |
| **Counsel patient on the psychoactive effects of hormones** | Some mood/mental health problems such as depression and anxiety may be addressed by hormones, others, including depression, anxiety and psychosis, may be exacerbated by hormones |
| **Summarize patient’s ability to provide informed consent** | Document patient’s:  Ability to communicate choice  Comprehension of clinical situation  Understanding of alternatives (hormones, surgery, no treatment), benefits, and risks  Review and sign consent document, document that patient is able to begin hormone therapy |
| **Schedule Follow Up Visits** | Initiation of hormone therapy visit (1 week) |

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| **Visit 4** | **Initiation of Hormone Therapy** |
| **Goals of the Session** | To review available medications  Method of delivery/use  Side effects  Timeline of expected results  Initiate treatment |
| **Activities** | |
| **Review medication table and order medication** | Review available medications, discuss side effects  Discuss patient’s preferred method of delivery (e.g., oral versus injectable)  Educate patient about realistic expectations for results and timeline of results  Order a 1 month supply of the medication |
| **Schedule Follow Up Visits** | Follow up medical visit within 4 weeks if oral med prescribed, 2 weeks if injection is prescribed  Behavioral Health or case management as needed  Order labs |

**Table 1: Initial Dosing Medication Table for MTF:** The usual regimen is an estrogen + anti-androgen.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **ESTROGENS:** Prescribe one month of ***ONE*** of the following hormones: | | | | |
| *Preferred Regimen:* | | | | |
| **Oral Estrogen** | Dose | Route & Frequency§ | Amount | Refills |
| Estradiol (Estrace) | 1.0mg | Oral, twice daily | 60 tablets | 0 |
| **Injectable Estrogen** | Dose | Route & Frequency§ | Amount | Refills |
| Estradiol Cypionate 5mg/ml | 0.5cc (2.5mg) | Intramuscular, every two weeks | 1.0cc | 0 |
| Estradiol Valerate 20mg/ml | 0.5cc (10mg) | Intramuscular, every two weeks | 1.0cc | 0 |
| *Alternate Regimen:* | | | | |
| **Oral Estrogen** | Dose | Route & Frequency | Amount | Refills |
| Premarin | 1.25mg | Oral, twice daily | 60 tablets | 0 |
| **Transdermal Estrogen** | Dose | Route & Frequency | Amount | Refills |
| Estradiol Patch \* | 0.05-0.1 mg | One patch topically, 2x/wk | 8 patches | 0 |
| \* Transdermal estrogen may be preferred in some circumstances, e.g. age over 45, history of venous thromboembolic disease or cardiovascular risk factors. Although most patches are applied twice weekly, this may differ by product. Goal is to provide an initial dose of 50-100 mcg transdermal estradiol daily.  § Some providers recommend administering oral estradiol sublingually or injectable estradiol subcutaneously. | | | | |

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| **ANTI-ANDROGENS:** Prescribe one month of ***ONE*** of the following anti-androgens.  **DHT-BLOCKERS:** Some clinicians use dihydrotestosterone blockers as a primary anti-androgen, although they are less effective than either spironolactone or flutamide. DHT-Blockers may also be added to traditional anti-androgens to minimize androgenic hair loss. | | | | |
| *Preferred Regimen:* | | | | |
| **Oral Anti-Androgen** | Daily Dose | Route & Frequency | Amount | Refills |
| Spironolactone | 100mg | Oral, single or divided doses daily | 1 month | 0 |
| *Alternate Regimen:* | | | | |
| **Oral Anti-Androgen** | Daily Dose | Route & Frequency | Amount | Refills |
| Flutamide (Eulexin) | 125 mg | Oral, twice daily | 60 tablets | 0 |
| **Oral DHT-Blockers** | Dose | Route & Frequency | Amount | Refills |
| Finasteride (Proscar) | 5mg | Oral, once daily | 30 tablets | 0 |
| Dutasteride (Avodart) | 0.5mg | Oral, once daily | 30 tablets | 0 |

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

**If preference is to inject:**

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

**Table 2: Initial Dosing Medication Table for FTM:** The usual regimen is testosterone.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **TESTOSTERONE:** Prescribe one month of ***ONE*** of the following hormones\*: | | | | |
| *Preferred Regimen:* | | | | |
| **Injectable Testosterone** | Dose | Route & Frequency§ | Amount | Refills |
| Testosterone cypionate or enanthate 200mg/ml§§ | 0.5cc (100mg) | Intramuscular, every two weeks | 1cc | 0 |
| *Alternate Regimen:* | | | | |
| **Transdermal Testosterone** | Dose | Route & Frequency | Amount | Refills |
| Testosterone gel 1% (Androgel, Testim)\*\* | 2.5-5mg | One packet topically, daily | 30 packets | 0 |
| Testosterone patch (Androderm) | 5mg | One patch topically, daily | 30 patches | 0 |
| \* A dihydrotestosterone blocker (e.g. Finasteride) at the usual male doses may be used in addition to testosterone to reduce androgenic hair loss.  \*\*Low-dose transdermal testosterone may be insufficient to stop menses, consider addition of depot medroxyprogesterone (DepoProvera).  § Some providers recommend administering injectable testosterone subcutaneously.  **§§ Important: Commercially available testosterone cypionate is usually suspended in cottonseed oil. Testosterone enanthate is usually suspended in sesame oil. Enquire about allergies before prescribing these medications.** | | | | |

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| **Agents not available in the USA** (See Appendix 5) Some clients may obtain hormones and anti-androgens from international pharmacies. |
| **FTM:**   * Testosterone undecanoate (oral) 160–240 mg/d * Dihydrotestosterone 10% cream applied topically (to clitoris) 20mg three times daily. (Prescribed by some surgeons 3 months before metoidioplasty to increase clitoral size; however, insufficient data on efficacy.) |
| **MTF:**   * Cyproterone Acetate 50-150 mg/day oral (an anti-androgen) |

**If preference is to inject:**

|  |  |  |
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| **FTM clients Injectable Testosterone** | Dose | Route & Frequency |
| Testosterone cypionate or enanthate 200mg/ml | 0.5cc (100mg) | Intramuscular, every two weeks |

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| **Visit 5** | **4 Week Medical Follow-Up** |
| **Goals of the Session** | To perform initial assessment after the initiation of hormone therapy  To continue hormone therapy  To continue the provision of primary care |
| **Activities** | |
| **Review Labs and order next round** | Liver enzymes  Lipids  Prolactin level, if MTF on estrogen  Electrolytes, if taking spironolactone  Complete blood count, if taking flutamide |
| **For injections** | Proceed with hormone injection after Medical Provider has reviewed the laboratory results and authorized continuation of the treatment  Ask if the patient is receiving injections from self or an other. If so, observe the injection technique  If the technique is sound, document approval for self-injection in the chart  If the technique needs improvement:  Offer instruction and support.  Schedule bi-weekly nursing appointments for further teaching and injections until the nursing provider assesses that the patient or other has learned the proper technique and can safely inject without supervision. |
| **Update history and physical exam** | Patient’s tolerance of hormones and anti-androgens  Any side effects patient may be experiencing  MTF client: Cessation of erections  FTM client: Cessation of menses |
| **Increase dosage of hormones** | See table below, prescribe one month supply |
| **Schedule Follow Up Visits** | Follow up medical visit within 4 weeks if oral med prescribed, 2 weeks if injection is prescribed  Behavioral Health or case management as needed |

**Table 3: Follow-Up Dosing Medication Table for Transgender Women (MTF)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **ESTROGENS:** Prescribe one month of ***ONE*** of the following hormones: | | | | |
| *Preferred Regimen:* | | | | |
| **Oral Estrogen** | Dose | Route & Frequency | Amount | Refills |
| Estradiol (Estrace) | 2.0mg | Oral, twice daily | 60 tablets | 0 |
| **Injectable Estrogen** | Dose | Route & Frequency | Amount | Refills |
| Estradiol Cypionate 5mg/ml | 1.0cc (2.5mg) | Intramuscular, every two weeks | 5.0cc | 0 |
| Estradiol Valerate 20mg/ml | 1.0cc (10mg) | Intramuscular, every two weeks | 5.0cc | 0 |
| *Alternate Regimen:* | | | | |
| **Oral Estrogen** | Dose | Route & Frequency | Amount | Refills |
| Premarin | 1.25mg | Oral, two tablets twice daily | 120 tablets | 0 |
| **Transdermal Estrogen** | Dose | Route & Frequency | Amount | Refills |
| Estradiol Patch | 0.1mg | Two patches topically, twice weekly | 16 patches | 0 |

**Table 3: Follow-Up Dosing Medication Table for Transgender Women (MTF) Continued**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **ANTI-ANDROGENS:** Prescribe one month of ***ONE*** of the following anti-androgens.  **DHT-BLOCKERS:** Some clinicians use dihydrotestosterone blockers as a primary anti-androgen, although they are less effective than either spironolactone or flutamide. DHT-Blockers may also be added to traditional anti-androgens to minimize androgenic hair loss. | | | | |
| *Preferred Regimen:* | | | | |
| **Oral Anti-Androgen** | Daily Dose | Route & Frequency | Amount | Refills |
| Spironolactone | 200mg | Oral, in divided doses daily | 1 month | 0 |
| *Alternate Regimen:* | | | | |
| **Oral Anti-Androgen** | Daily Dose | Route & Frequency | Amount | Refills |
| Flutamide (Eulexin) | 125 mg | Oral, twice daily | 60 tablets | 0 |
| **Oral DHT-Blocker** | Dose | Route & Frequency | Amount | Refills |
| Finasteride (Proscar) | 5mg | Oral, once daily | 30 tablets | 0 |
| Dutasteride (Avodart) | 0.5mg | Oral, once daily | 30 tablets | 0 |

**Table 4: Follow-Up Dosing Medication Table for Transgender Men (FTM)**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **TESTOSTERONE:** Prescribe one month of ***ONE*** of the following hormones: | | | | |
| *Preferred Regimen:* | | | | |
| **Injectable Testosterone** | Dose | Route & Frequency | Amount | Refills |
| Testosterone cypionate or enanthate 200mg/ml | 1.0cc (200mg) | Intramuscular, every two weeks | 2cc | 0 |
| *Alternate Regimen:* | | | | |
| **Transdermal Testosterone** | Dose | Route & Frequency | Amount | Refills |
| Testosterone gel 1% (Androgel, Testim) | 5mg | One packet topically, daily | 30 packets | 0 |
| Testosterone patch (Androderm) | 5mg | One patch topically, daily | 30 patches | 0 |

**For Injections:**  If the patient chose injection by themself or SOFFA and provider approved the injection technique, prescribe:

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

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

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| **Visit 6** | **4 Week at Full Dose Medical Follow-Up** |
| **Goals of the Session** | To perform assessment after a change of hormone therapy  To continue hormone therapy    To continue the provision of primary care |
| **Activities** | |
| **Review Labs and order next round** | Liver enzymes  Lipids  Prolactin level, if MTF on estrogen  Electrolytes, if taking spironolactone  Complete blood count, if taking flutamide |
| **For injections** | Proceed with hormone injection after Medical Provider has reviewed the laboratory results and authorized continuation of the treatment  Ask if the patient is receiving injections from self or an other. If so, observe the injection technique  If the technique is sound, document approval for self-injection in the chart  If the technique needs improvement:  Offer instruction and support.  Schedule bi-weekly nursing appointments for further teaching and injections until the nursing provider assesses that the patient or other has learned the proper technique and can safely inject without supervision. |
| **Update history and physical exam** | Patient’s tolerance of hormones and anti-androgens  Any side effects patient may be experiencing  MTF client: Cessation of erections  FTM client: Cessation of menses |
| **Prescribe hormones** | Prescribe three months of ONE of the hormones and anti-androgens as outlined in Visit 5 |
| **Schedule Follow Up Visits** | Medical visit in 3 months  Lab visit one week prior to medical visit  Supportive counseling and education session in 1 month, if the need is identified  Nursing visits for injection teaching as needed |

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| **Visit 7** | **3 Months after initiating hormones** |
| **Goals of the Session** | To continue health assessment after the initiation of hormone therapy  To continue hormone therapy  To continue the provision of primary care |
| **Activities** | |
| **Review Labs and order next round** | Complete blood count  Comprehensive metabolic panel (liver enzymes, electrolytes, lipid panel)  Prolactin (for MTF on estrogen) |
| **For injections** | Proceed with hormone injection after Medical Provider has reviewed the laboratory results and authorized continuation of the treatment  Ask if the patient is receiving injections from self or an other. If so, observe the injection technique  If the technique is sound, document approval for self-injection in the chart  If the technique needs improvement:  Offer instruction and support.  Schedule bi-weekly nursing appointments for further teaching and injections until the nursing provider assesses that the patient or other has learned the proper technique and can safely inject without supervision. |
| **Update history and physical exam** | Patient’s tolerance of hormones and anti-androgens  Any side effects patient may be experiencing  How transition is going  Cessation of erections/cessation of menses |
| **Prescribe hormones** | Prescribe hormones, anti-androgens, syringes and needles for 6 months |
| **Schedule Follow Up Visits** | Medical visits every 6 months with lab visits one week prior and appointments for refills as needed.  Supportive counseling and education sessions and psychiatric consultations offered whenever the need is identified.  Continue routine, age-appropriate health care maintenance, including screening for sexually transmitted diseases if appropriate. |

**Special Considerations**

1. **Hormone-Experienced Clients**

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

2. **Clients who have undergone gonadectomy (removal of the testes or ovaries)**

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

3. **Clients over 45 years/smokers**

* Oral estrogens confer an increased risk of thromboembolic disease. Transdermal or parenteral routes are preferred over oral estrogen. Conjugated estrogen (Premarin) is not recommended.
* Consider addition of aspirin

4. **HIV infection (see Appendix 3 – Managing Comorbidities)**

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

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**Appendix A** **CONSENT FORM**

|  |  |  |
| --- | --- | --- |
| new logo small for | **INFORMED CONSENT** **FOR HORMONE THERAPY** | |
| **MRN:** | **Name:** |
| **DOB:** | **PCP:** |

The goal of this consent form is to review the potential risks and benefits associated with use of cross-gender hormone therapy. The full medical effects and safety of hormone therapy are not fully known. Smoking, drinking alcohol, and unmanaged medical problems can increase the likelihood of an adverse effect. Potential adverse effects may be permanent and may include, but are not limited to:

* Increased risk for heart disease, heart attack, or stroke
* Blood clots
* Tumors or cancer of the breasts or pituitary gland (a small gland in the brain)
* Liver inflammation
* Anemia (decreased number of red blood cells)
  + - Acne
    - Increased or decreased sex drive and sexual functioning
    - Depression, anxiety, or other mental health symptoms (especially if experiencing symptoms prior to treatment)

By signing below:

* I agree that my medical provider has discussed with me the nature and purpose of hormone therapy, the benefits and risks, and all feasible alternative diagnostic or treatment options.
* I attest that I understand and accept the risks involved.
* I have had sufficient opportunity to discuss my condition and treatment with the medical provider, nursing staff, and/or other staff, and all of my questions have been answered to my satisfaction.
* I authorize and give my informed consent for the provision of hormone therapy at the Institute for Family Health

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Signature of Client Date Legal Name of Client (Printed)

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Signature of Witness Date Name of Witness and Relationship (Printed)

**Appendix B** **Managing Co-morbidities**

* **Mental Health Conditions and Substance Abuse**

While not an absolute contradiction, the presence of pre-existing mental health conditions (e.g., depression, suicidal ideation, psychosis) may negatively impact a patient’s ability to provide informed consent for hormone therapy. If a patient presents with an active mental health condition that is not centered on their gender identity, the patient should be stabilized with psychotropic medications and/or psychotherapy before beginning hormone therapy. In this case a mental health professional with experience in transgender care must confirm the patient’s ability to consent to treatment at the time hormone therapy is initiated. Similarly, Substance use and abuse is not an absolute contraindication to hormone therapy. Individual who present for care under the influence are not considered able to provide informed consent at that moment and should be reassessed when not under the influence. In some cases, hormone therapy may increase the likelihood of patients engaging in treatment for substance use and may improve overall mental health outcomes. When making referrals it is important to ensure that the program will affirm the patient’s gender identity.

* **Cigarette Smoking**

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

* **Coronary Artery Disease**

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

* **History of Deep Venous Thrombosis, Pulmonary Embolism or Embolic Stroke**

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

* **Liver Disease**

If the patient has a self-limited hepatic infection, such as acute Hepatitis A or B, initiation of hormone therapy should be delayed until the patient is in the convalescent stage and transaminases have returned to normal. If the patient has chronic hepatitis for which treatment is available, such as Hepatitis C, treatment should be pursued. Patients with chronic hepatitis should be closely monitored during initiation of hormones or hormone dosage change. If transaminases (ALT) increases 2 times above baseline then consultation with hepatologist is advised. Transdermal/parenteral hormones are preferred to oral administration. For all patients with chronic liver disease, the primary care provider should minimize the risk of further liver injury with appropriate immunizations and behavioral interventions.

* **Pituitary Adenoma**

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

* **Uncontrolled Diabetes**

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

* **Uncontrolled Hypertension**

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

* **HIV Infection**

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

**Appendix C** **MANAGING LABORATORY ABNORMALITIES**

* **Anemia**

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

* **Erythrocytosis**

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

* **Elevated Prolactin Level**

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

**Guidelines for Elevated Prolactin Level**

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

* **Elevated Transaminases (LFTs)**

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

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

**Appendix D**

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

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| **Table 2: Anti-Androgens** | | | | | | | | | |
| **MEDICATION** | **INITIAL DOSE** | | **MAXIMUM DOSE** | | **INTENDED EFFECTS** | | **POSSIBLE SIDE EFFECTS** | | **LABS TO** MONITOR |
| Spironolactone  (Aldactone) 25mg, 50mg, 100mg | 75-100 mg  Orally in divided daily dosing | | 200-400mg  Orally in divided daily dosing | | Decrease of androgenic alopecia  Impotence  Thinning and decrease of body and facial hair  Hypertrophy of breasts | | Ataxia  Gastric ulcer  Gastronintestinal upset  Headache  Hirsutism  Hyperkalemia  Hyponatremia  Hypotension  Mood Changes | | Electrolytes |
| Flutamide  (Eulexin) 125mg | | 125 mg  Orally, twice daily | | 125 mg  Orally, twice daily | | Anemia  Gastrointestinal upset  Hot flashes  Impotence  Loss of libido  Mood Changes  Rash  Testosterone elevation\* | | Complete Blood count  Liver enzymes | |
| Finasteride  (Proscar) 5mg  (Propecia) 1mg | 1mg  Orally, once daily | | 5mg  Orally, once daily | | Decrease of androgenic alopecia | | Decreased libido  Impotence  Mood Changes  Testosterone elevation\* | | Liver enzymes |
| Dutasteride  (Avodart) 0.5mg | | | 0.5mg  Orally, once daily | | | | 0.5mg  Orally, once daily | | |
| Cyproterone acetate (Androcur®) | 50mg | | 150mg | | Decrease of androgenic alopecia  Impotence  Thinning and decrease of body and facial hair  Hypertrophy of breasts | | Thromboembolic events  Hepatic toxicity  Benign and malignant liver tumors  Intraabdominal hemorrhage  Meningioma  Anemia  Depression | | Complete Blood count  Liver enzymes  Electrolytes |
| \* Dutasteride, finasteride and flutamide may cause a transient elevation in testosterone that is probably not clinically significant | | | | | | | | | |

**Choosing an Anti-Androgen**

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

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

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| **Table 3: “Masculinizing” Regimens** | | | | | | | |
| **MEDICATION** | **INITIAL DOSE** | | **MAXIMUM DOSE** | **INTENDED EFFECTS** | **POSSIBLE SIDE EFFECTS** | | **LABS TO DRAW** |
| Testosterone Cypionate  100mg/ml  Or  200mg/ml | 100 mg  Intramuscularly, every two weeks  -----------------------  Same dose for post-oophorectomy men | | 200 mg Intramuscularly, every two weeks  -----------------------  100 mg  Intramuscularly, every two weeks  for post-oophorectomy men | Clitoral hypertrophy  Growth of facial and body hair  Increase in muscle mass and definition  Increase of androgenic alopecia  Lowering of vocal pitch | Acne  Amenorrhea  Androgenic alopecia  Depression  Gastrointestinal upset  Headache  Hepatitis  Hyperlipidemia  Hypertension  Mood Changes  Polycythemia | | Complete Blood Count  Lipids  Liver enzymes  Prolactin |
| Testosterone Enanthate\*  100mg/ml  Or  200mg/ml | | | 100 mg  Intramuscularly, every two weeks  -----------------------  Same dose for post-oophorectomy men | | 200 mg Intramuscularly, every two weeks  -----------------------  100 mg  Intramuscularly, every two weeks  for post-oophorectomy men | | |
| Testosterone gel (Testim or Androgel) 1mg/g (1%) | | | 2.5mg  Topically daily | | 5-10 mg Topically daily | | |
| Testosterone patch (Androderm)  2.5mg or 5mg | | 2.5mg  Patch daily | | 5mg  Patch daily | | As above  Local irritation | |
| \* Testosterone Enanthate is supplied only in 5cc vials. Therefore, it is not listed as an option in the parts of the protocol that require prescribing less than 5cc. If a patient is hormone experienced and already taking Testosterone Enanthate, this can be substituted for Testosterone Cypionate. | | | | | | | |

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| **Table 4A: Masculinizing Effects in FTM Clients Receiving Testosterone** | | | |
| **EFFECT** | **ONSET (MONTHS)** | | **MAXIMUM (YEARS)** |
| Skin oiliness/acne | 1-6 | | 1-2 |
| Facial hair | 6-12 | | 4-5 |
| Androgenic hair loss (scalp) | | 6-12 | |
| Increased muscle mass | 6-12 | | 2-5 |
| Fat redistribution | 1-6 | | 2-5 |
| Cessation of menses | | 2-6 | |
| Clitoral enlargement | 3-6 | | 1-2 |
| Vaginal atrophy | 3-6 | | 1-2 |
| Deepening of voice | 6-12 | | 1-2 |
| **Table 4B: Feminizing Effects in MTF Clients Receiving Estrogen and Anti-Androgen** | | | |
| **EFFECT** | **ONSET (MONTHS)** | | **MAXIMUM (YEARS)** |
| Decrease in muscle mass and strength | 3-6 | | 1-2 |
| Softening of skin | 3-6 | | unknown |
| Decreased erections | 1-3 | | 3-6 |
| Breast growth | 3-6 | | 2-3 |
| Decreased testicular volume | 3-6 | | 2-3 |
| Decreased sperm production | Unknown | | >3 |
| Voice changes | | none | |
| Adapted from The Endocrine Society Clinical Practice Guidelines, 200 | | | |

**Appendix E**

**Insert Competency Document(s) Here**

**SECTION III: Best Practices for Assessment and Care for Individuals Seeking Gender Confirmation Surgery**

While IFH does not provide gender-confirmation surgery or procedures, patients interested in this path may pursue a behavioral health and medical evaluation to satisfy eligibility criteria for the surgery team they elect to work with during the process. Consistent with best practices put forth in the current Standards of Care (WPATH – formerly the Harry Benjamin Standards), gender-confirmation surgery is generally no longer considered part of a mandatory vetting process that involves mental health provider diagnosing a disorder and providing “clearance” for the individual to pursue surgery. Rather, many providers and surgery teams consider a comprehensive approach to providing counseling, medical care, hormone therapy, a minimum amount of time spent living as the identified gender, and letters of recommendation a crucial approach to ensuring the best possible outcomes (emotionally and physically). In general best practices suggest that the following steps constitute best practices in approaching the issue of gender confirmation surgery:

* Initial biopsychosocial assessment to rule out and address underlying mental health issues and case management issues that may complicate response to treatment
* Initial medical assessment to ensure adequate health maintenance for routine or more complex health issues
* 12 months of continuous hormone therapy in preparation for surgery
* Pre-operative medical consultation to ensure patient is medically cleared and stable for surgery
* Letters of recommendation reflecting that patient has been living as the identified gender continuously for at least 1 year and that gender dysphoria is the only factor motivating the patient for surgery

While ongoing psychotherapy is not mandated for treatment at IFH, patients are strongly encouraged to maintain a relationship with a trusted and culturally competent behavioral health provider to help facilitate care, coordinate services, and provide support to the patient and family during the transition process.

**Sample of Items that May Need to Be Documented for Surgery Eligibility**

* Patient has been adherent with at least 12 months of continuous hormone therapy
* Patient has had at least 12 months of continuous experience living as the identified gender
* Patient has been evaluated for the ability to provide informed consent and is deemed to have been medically and psychiatrically stable for at least 6 months
* Patient’s rationale for surgery
* Patient has been adherent with the WPATH standards of care
* Patient has engaged with treatment team and will continue to seek support after surgery
* Patient demonstrates understanding of the surgery and appears prepared to cope with any and all outcomes following surgery (including lack of desired outcome or potential complications)