JOHNS HOPKINS UNIVERSITY STUDENT HEALTH & WELLNESS CENTER POLICY & GUIDELINES MANUAL	*Document Number*	
Subject: **Gender Affirming Hormone Therapy Policy**	*Created*	9/28/2021
	Page(s)	6
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Revised:		

POLICY

Gender affirming hormone therapy, otherwise known as feminizing or masculinizing hormone therapy, is a medical necessity and considered to be a primary care service for many transgender and non-binary (TGNB) individuals. There are no randomized control trials that apply to gender affirming hormone therapy alone, however many retrospective studies have been done evaluating individuals who have used hormones and had gender affirming surgery (sex reassignment surgery). The research has shown significant improvements in gender dysphoria and psychosocial outcomes, as well as a very low percentage of individuals who regret their treatment. Not all people who identify as TGNB will seek gender affirming therapy. If they desire to express a gender different than the sex they were assigned at birth on a consistent basis, hormone therapy can provide an option for bringing the endocrine and psychological systems into balance. In addition, medical visits relating to gender affirming hormone therapy provide an opportunity for broader health care and maintenance by establishing rapport and trust in a population that is often medically underserved.

By providing the initiation and maintenance of gender affirming hormones at SHWC and UHS, Johns Hopkins University students who identify as TGNB will be given the same opportunity as their cis-gender peers to obtain essential primary care services on campus, enhancing not only their psychosocial outcomes but also their ability to focus on their academics.

PURPOSE

- To minimize barriers to care (e.g., cost, time spent and access to care) for students who wish to use masculinizing or feminizing hormones.
- To improve psychosocial outcomes, and thereby academic potential, for transgender and non-binary (TGNB) students by providing accessible comprehensive primary health care on campus.
- To improve the health of all TGNB students by increasing trust between SHWC/UHS and the TGNB student community.
- To help students establish positive health behaviors and continuity of care that can be sustained throughout their lives thus decreasing future negative health consequences or morbidities.

- To delineate roles and establish requirements for competencies and privileging for clinicians in who provide gender affirming services and gender specific care for TGNB students.

PROCEDURE

1. Clinicians providing gender affirming services at SHWC/UHS must be appropriately trained in providing TGNB care and be granted privileges by the Chief Medical Officer. Clinicians should have didactic as well as clinical training documented in their personnel record and have a desire to serve the TGNB population. Clinicians must also:
    a. Be knowledgeable about all basic medical options available to TGNB persons.
    b. Understand and be able to educate clients on information about the medication options including risks, benefits, expected results, and all information in the appropriate informed consent.
    c. Refer clients to a mental health, surgical or other provider as requested by the client or deemed appropriate by staff.
    d. Discuss the availability of insurance coverage and reimbursement through the Student Health Plan (SHP) or Employee Health Plan (EHP) for gender affirming services.
2. To be granted these privileges, clinicians must write a letter to the Chief Medical Officer requesting privileges documenting their education and training in the specialty and stating why they would like to provide gender affirming hormones to clients. Privileges will be granted based on the Chief Medical Officer's discretion and will be re-evaluated on a bi-annual basis. This re-evaluation will be based on chart reviews and the clinician's experience providing this care at SHWC/UHS.
3. Clients requesting an initial visit for gender affirming hormone therapy will be given a one hour visit with the clinician in order to provide thorough education and review of the informed consent. Subsequent or follow up visits will be scheduled for no less than 30 minutes.
4. **Informed Consent** – clients requesting gender affirming hormone therapy must be educated on the known risks, permanent effects of the treatment, and that the use of medications for gender affirming therapy is considered "off-label" use.
    a. Clients must meet the following requirements to be candidates for gender affirming hormone treatment at SHWC/UHS:
        i. 18 years or older
        ii. Able to give informed consent
        iii. Be able to verbalize persistent gender identity that does not match assigned gender at birth
        iv. If significant medical or mental health concerns are present, they must be well-managed including demonstration of an ongoing relationship with a medical and/or mental health provider as appropriate
        v. Be able to participate in the informed consent process, including a verbalized understanding that:
            1. Some physical changes from gender affirming hormone therapy are permanent.
            2. Future fertility may be impacted by use of gender affirming hormones
    b. All clients requesting gender affirming hormone therapy will be:
        i. Given written information on the use, effectiveness, and medically recognized risks and benefits of the therapy.

ii. Educated on the role of hormone therapy may play on their fertility and ability to have biological children and be informed about options for preserving future fertility.
iii. Given local resources available for concerns related to gender identity

c. At their initial visit, the Informed Consent for either Feminizing Hormone Therapy or Masculinizing Hormone Therapy (see attached) will be thoroughly reviewed by the clinician and client.
d. For individuals under age 18, SHWC/UHS may facilitate ongoing gender affirming hormone care that has been established prior to matriculation if that care is consistent with this policy. The consent of at least one parent or guardian is the standard of care nationally for TGNB individuals who have not reached the age of majority.

5. **Medical Screening and Evaluation**
   a. A complete medical, surgical, social and sexual history must be completed at the initial visit and updated at least annually or with reported changes.
   b. Initial physical exam must include vital signs (blood pressure, height, and weight), lung, heart, and thyroid exam. Other targeted exams should be recommended as indicated (breast, pelvic exams) by current evidence and standards of care for all persons.
   c. Consultation with an Endocrinologist or Hematologist may be considered prior to initiation of gender affirming therapy based on prior history or current evidence of medical conditions that could be affected by hormone use. Examples of conditions include diabetes mellitus or a history of thromboembolic event.
   d. Required follow up exams will occur at 3 months, 6 months, 9-12 months and then every 6-12 months thereafter.
      i. Students must be able to schedule their recommended follow up appointments at SHWC/UHS in order to continue to receiving a prescription for hormones. They will be advised to plan accordingly if they have plans to travel abroad or home during the summer break.
6. **Baseline Labs and Prescription Initiation**
   a. For patients requesting **feminizing hormones (MTF):**
      i. Baseline labs: BUN, creatinine, and potassium.
      ii. Hormone Prescriptions:
         1. **Estradiol**:
            a. Oral Estradiol – guidelines state 1-8mg per day. Starting dose = 2-4mg per day. Maximum dose = 8mg per day (if > 2mg recommend divided BID dosing).

            OR

            b. Estradiol valerate 20mg IM q 2 weeks. Maximum dose = 40mg IM q 2 weeks. (May divide into weekly injections for cyclical symptoms)
         2. **Anti-androgens**:
            a. Spironolactone 50 mg PO BID (initial dose). Maximum dose = 200mg PO BID.***

            ***Considered first line therapy for testosterone blockade.

            b. Finasteride 1-5mg PO q day
            c. Dutasteride 0.5mg q day

            OR

            d. Injectable GnRH agonists (Lupron) if none of the other anti-androgens are possible.
         3. **Progestogens** (as requested and/or deemed appropriate by provider):

***** "Many transgender women and providers alike report an anecdotal improved breast and/or areolar development, mood, or libido with the use of progestogens. There is no evidence to suggest that using progestogens in the setting of transgender care are harmful." (UCSF Guidelines, Feminizing hormone therapy)

a. Micronized progesterone 100mg PO qhs (initial dose) – 200mg PO qhs (maximum dose).

b. For patients requesting **masculinizing hormones (FTM):**
   i. Baseline labs: hemoglobin and hematocrit.
   ii. Hormone Prescriptions:
      1. Testosterones cypionate or testosterone enanthate 200mg/mL:
         a. Initial dosing – 20mg (low-initial dose) – 50mg (0.25ml) subcutaneous or IM q week.
         b. Maximum dosage – 100mg (0.5ml) subcutaneous or IM q week.

         *** If using q 2-week dosing, double the doses.

      2. Testosterone topical gel 1%
         a. Initial dosing – 12.5-25mg (low initial dose) – 50mg q a.m.
         b. Maximum dosage – 100mg q a.m.

c. **Syringe and needle prescriptions:** For any injectable hormone, the patient will also need a prescription written for 1ml syringes, 18g needles (to draw up medication), and either 25g 5/8-inch needles (for subcutaneous injections) or 22g – 23g one-inch needles (for IM injections).

7. **Periodic Physical Exams and Recommendations for Preventive Tests**
   a. Required follow up exams will occur at 3 months, 6 months, 9-12 months and then every 6-12 months thereafter.
   b. At each follow up the patient will be asked about any changes in medical/surgical/social/sexual histories, signs, and symptoms of potential complications related to the medications they are taking and a blood pressure will be obtained.
      i. For patients on **feminizing hormones** the following measures will be assessed:
         1. Subjective: mood changes, libido changes, headaches, vision changes, pain or swelling in legs, chest pain, nipple discharge/tenderness, frequency of erections (spontaneous and stimulated), testicles decreasing in size, depression, anxiety, sleep disturbances, breast growth/development, changes in hair growth
         2. Objective: vital signs, general appearance.
         3. Review medication dosing and verify usage is consistent with prescription and directions
         4. Tobacco usage will be assessed and cessation options reviewed.
         5. Labs:
            a. Routine – BUN/creatine, potassium, total testosterone, estradiol.
            b. PRN – prolactin (only if symptoms of possible prolactinoma are present).

ii. For patients on **masculinizing hormones** the following measures will be assessed:
    1. Subjective: mood changes, libido changes, status of menses, sexual changes including size of clitoris, male pattern hair growth, acne, voice deepening, changes in body fat distribution
    2. Review medication dosing and verify usage is consistent with prescription and directions.
    3. Labs: Total testosterone (need to know when last testosterone injection was so that can be clear whether result will be peak or trough) hemoglobin and hematocrit

8. **Titration of Dosages of Hormones**
    a. Feminizing hormones and androgen blockers:
        i. Titration upwards of dose should be driven by patient goals, in the context of clinical response, hormone level monitoring, and safety monitoring (e.g. presence of risk factors such as smoking, renal functions and K+ in patients using spironolactone).
            1. According to the Endocrine Society target range of total testosterone should be <55ng/dl
        ii. The general approach for titration would include increasing of both estrogen and antiandrogen dosing until the estrogen dose is in the female physiologic range. Once this has been achieved titration efforts can focus on increasing androgen blockage. (UCSF Guidelines, Feminizing hormone therapy)
        iii. For androgen blockade maintain current physiologic estrogen and dosing and titrate upward on antiandrogens and/or addition of a progestogen until testosterone is physiologically suppressed based on blood work results.
    b. Masculinizing Hormones:
        i. Titration upwards of dose should be driven by patient goals, in the context of clinical response, hormone level monitoring, and safety monitoring (i.e. hemoglobin hematocrit).
        ii. Clinical response can be measured objectively by the presence of amenorrhea by 6 months.
        iii. Once within the normal male physiologic range, there is no evidence that higher doses/levels of testosterone result in a greater degree of virilization. Lab reference ranges for total testosterone levels are generally very wide (roughly 350-1100ng/dl); if men have testosterone levels at the lower end of the normal male range and are either concerned about slow progress or are having symptoms of low energy, libido, or mood, it is reasonable to slowly increase the dose while monitoring for side effects.
        iv. Once total testosterone is greater than the midpoint value in the lab reported reference range, it is unclear if an increase in dose will have any positive effect on perceived slow progress, or on mood symptoms or other side effects.

REFERENCES

1. WPATH Standards of Care, Volume 7

2. Hembree et al. (2017). Endocrine Treatment of Gender-Dysphoric/Gender-Incongruent Persons: An Endocrine Society Clinical Practice Guideline. *Journal of Clinical Endocrinology and Metabolism*, 102(11): 1-35. doi: 10.1210/jc.2017-01658

3. UCSF Transgender Care, Department of Family and Community Medicine, University of California San Francisco. Guidelines for the Primary and Gender-Affirming Care of Transgender and Gender Nonbinary People; 2nd edition. Deutsch MB, ed. June 2016. Available at transcare.ucsf.edu/guidelines.