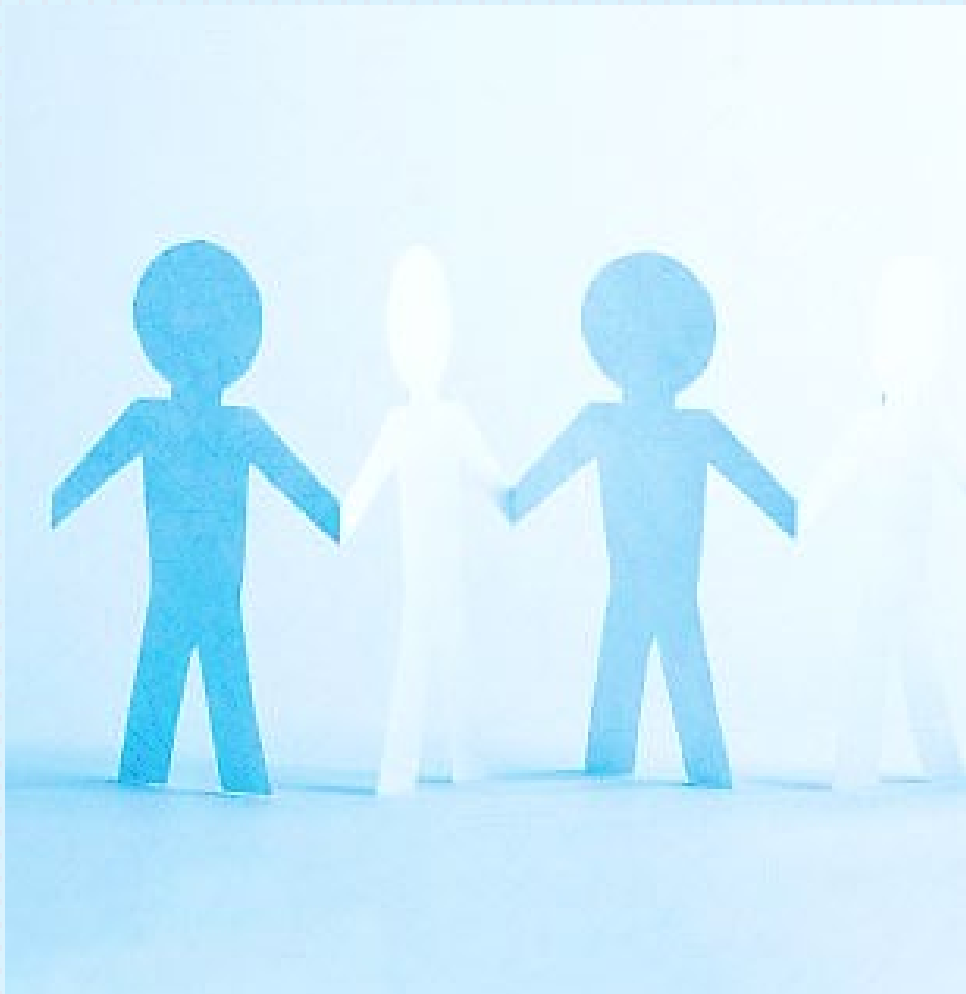


Medical Care of Gender Diverse Children and Adolescents

SPRING 2019



Protocol for the Gender Affirming Care of Transgender, Non-binary, and Gender Diverse Children and Adolescents

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01. Overview: Treatment of Gender Diverse Young People

Fenway's mission is to serve sexual and gender minority individuals with respect and dignity through an integrated health care model with the goal of increasing access to care and decreasing stigma. Children and adolescents are included in this mission and our goals. We strive to listen to our gender diverse patients and their families and to provide them with supportive and empowering health care. Fenway Health utilizes a team approach to transgender and gender diverse medical care that includes a primary medical provider, a behavioral health specialist (BHS), a Transgender Health patient advocate, medical case management, and other ancillary supports necessary to create a holistic approach to gender affirming services for gender diverse youth and their families.

Initiation of Care

Patients may initiate care either through the Behavioral Health or the Medical Department. All patients will be encouraged to engage in the team approach in seeking medical gender affirmation, including using the services of both medical and mental health professionals (MHP). Whether a minor patient is pre-pubertal and seeking puberty suppression or is post-puberty and seeking gender affirming hormone treatment (GAHT), all patients and their families will be encouraged to engage with a MHP to enhance and maintain emotional health and supports as patients, along with their families, and to best navigate medical and/or social pathways to affirm and express their gender.

Legal Status and Provision of All Care

Legal status and custody issues must be determined at the initial visit. The chart must include the names and contact information of all legal guardians. Divorced and separated parents may have different degrees of legal authority over medical decision-making; this must be determined prior to any extensive assessment or treatment for gender confirmation.

Patients in DCF custody must have the name and contact information of the DCF caseworker in the chart. Approval of DCF to proceed with assessment must be documented in the chart. Initiation of internal DCF practices to attain court approval for the use of puberty blockers and/or gender affirming hormones should be started as soon as possible after the beginning of the gender affirming treatment assessment process.

Behavioral Health Assessment

All patients under 18 years of age considering pubertal suppression and/or GAHT will be expected to be assessed individually for readiness and appropriateness for initiating gender affirming medical treatment through

Fenway Behavioral Health or through an outside licensed MHP as appropriate. Family therapy will be encouraged when appropriate to the needs and concerns of the youth and their family. Families (parents or guardians) that need support during the patient's process of gender affirmation, whether the youth needs additional supports or not, will be encouraged to engage in behavioral health supports for their own needs and to optimize support of the patient. Outside MHPs should be experienced in treating gender dysphoria in children and adolescents. Ongoing and regular communication between the patient's Fenway Health medical team and outside MHP is expected and should be clearly documented in the chart.

If available and necessary, a Fenway-based Behavioral Health assessment may be provided over several sessions. The purpose of the assessment is to clarify goals for pubertal suppression and/or GAHT and to support the patient and their parents/guardians through the initial steps of gender affirmation. Depending on availability and necessity, a patient may be eligible to receive Fenway-based Behavioral Health supports after the assessment and during the ongoing process of gender exploration and gender affirmation. For patients who have initiated care in the Fenway Behavioral Health Department, the patient and/or their guardians may request the behavioral health provider to assist in scheduling an appointment for consultation with a Fenway medical provider for gender affirming care.

Prior to starting GAHT and/or puberty suppression, the medical provider will review any MHP assessment and referral report regarding gender affirming medical treatment for the patient. The Fenway medical provider may request/require an assessment and report on the patient's gender identity development and history from an outside MHP or internal BHS or MHP. This protocol allows flexibility for those atypical circumstances in which a behavioral health assessment is deemed unnecessary by the medical provider. Any variance from requiring a behavioral health assessment prior to initiation of gender affirming medical treatment will be documented in the patient's chart citing rationale and information to support this exception. As needed, or requested, any medical provider may bring a case to the monthly Transgender Health Youth Clinical Team (TYCT) or the weekly Transgender Health Clinical Team (TCT) meetings for consultation on the necessity of a behavioral health assessment of a patient's appropriateness for gender affirming medical treatment or for any other supports in question.

Fenway Health recognizes that there may be extenuating circumstances when behavioral health care may not be accessible or necessary for all patients and families. All patients will be offered information on accessing gender affirming behavioral health services and will be presented with the supports available to establish behavioral health care when needed to provide a therapeutic space for education, advocacy, and exploring gender affirmation, social stigma, and other

potential challenges faced by patients and families during the gender affirmation processes. Whether there are behavioral health services provided to the patient, the family, or both, the patient's mental health status and suicidality need to be assessed and monitored within medical care visits and in collaboration between the medical provider and the patient's MHP when present.

To expedite the gender affirming treatment assessment and referral process, the Youth GAHT Assessment and Referral Report (See Appendix A) will be sent to any outside MHP by the medical provider or BHS on the patient's care team at the time the patient indicates an interest in gender affirming medical treatments. As appropriate, documentation of a behavioral health assessment and referral report for gender affirming medical treatment will be included in the patient's chart. Prior to initiation of any medical treatment for puberty suppression and/or GAHT, a signed consent to this/these treatment(s) from all legal guardians must be placed in the patient's chart.

See Appendix A for the guideline on areas to include in the assessment and recommendations for puberty suppression or GAHT.

02. Medical Assessment

The patient must attend appointments accompanied by at least one, and preferably all, parents/legal guardians. The medical assessment includes collection of medical, social, psychiatric, and gender developmental histories; appropriate physical exams, baseline lab tests, and review of and consultation with any behavioral health provider who has provided a behavioral health assessment of the patient.

Guardians should be asked to provide consent for release of medical records from the patient's past/current outside medical providers. Providers should request growth charts, problem lists, medications list, vaccine record, and a complete copy of the patient's last annual physical exam (not a school note). Other records requested should be based on the patient's history of treatment and concerns.

Histories will include:

- History of gender identity development and pubertal development and any reported and/or observed symptoms of gender dysphoria or incongruence
- History of any gender-affirming measures including any efforts at social transition
- Past and current medical and social history and family history
- Past and current history of mental health management, all diagnoses, interventions, medications, hospitalizations, self-harm, disordered eating, and suicidal thoughts or actions.

Physical Exam

- Physical examination, with attention to development of secondary sex characteristics, Tanner staging, height and weight.
- Genital and chest examination may be deferred if the child's chronological age and known pubertal Tanner staging make puberty blockade medically unnecessary or the severity of the dysphoria could result in significant emotional distress to the child. In this instance, other means to assess Tanner staging may be necessary to negotiate with the patient and/or guardians.
- If the child's age and probable Tanner stage suggests a medically and socially appropriate use for puberty suppression, then a genital and chest examination is necessary.

Baseline Lab Evaluation for Puberty Suppression

- Serum estradiol and/or testosterone depending on sex assigned at birth: LH; FSH; and liver function.
- Consider other blood testing based on history or physical examination
- Consider bone age (radiograph of left hand) if specific concerns around development of height
- Consider vitamin D screening on individuals at greater risk for low bone density—low body weight/disordered eating, inactivity, inadequate calcium intake, poor diet, certain medical conditions, or treatment associated with reduction of bone mineral density (BMD) [1-8]
- Consider baseline bone densitometry, or central dual-energy x-ray absorptiometry (DEXA) scan to guide treatment decisions for children and adolescents identified at risk for skeletal fractures or if a patient is expected to require pubertal suppression for more than 2 years.[1, 8] Those potentially at risk include youth with primary bone disorders or potential for secondary bone disease such as those with chronic inflammatory disorders, IBS, anorexia nervosa, or cerebral palsy. (see *Appendix D for further information on bone health and management*)

Baseline Lab Evaluation for GAHT without Puberty Suppression

If planning to start testosterone:

- HCT
- Consider fasting blood glucose and/or glycated hemoglobin (A1c) and liver function tests if a patient's

exam or history suggest polycystic ovarian syndrome (PCOS), diabetes, or pre-diabetes

- Lipid profile if indicated based on current USPSTF guidelines, with regard to personal risk factors and family history
- Urine hCG if a patient is at any risk of pregnancy
- Consider serum testosterone if history or exam suggest PCOS or other androgenizing condition

If planning to start estradiol (and spironolactone):

- Basic metabolic panel
- Lipid profile if clinically indicated by age, family history, or cardiovascular risk
- Consider liver function tests if patient will be taking oral estrogen AND has a history of liver disease or dysfunction
- Consider baseline testosterone level in transfeminine individuals only if history of puberty, sexual functioning, or physical maturation is not as expected
- Baseline prolactin levels are only necessary in patients with a history of hyperprolactinemia or pituitary adenomas, or those who have been taking medications that may increase prolactin levels such as anti-psychotics

Baseline Lab Tests for All Gender Diverse Patients

- HIV test, viral hepatitis (A, B, and C), RPR, gonorrhea, and chlamydia based on patient assessed risk of exposure to each
- Other lab work may be considered based on patient individual medical history and physical exam and clinical judgment

Additional Non-Medical Assessments and Discussion

- Assessment of knowledge about and education on effects/benefits and risks of pubertal suppression and/or GAHT, including potential permanent loss of fertility and GAHT-dependent anatomical changes
- Discuss extent and timing of social transition - where, when, and to what extent desired
- Discuss with patient and parents/guardians to whom, when, and how to disclose to other family and social contacts, school, etc.

- Discuss safety issues around social transitioning, including risk of bullying and support the development of effective and safe coping skills by patient to manage potential negative responses
- Provide resources for assistance and advocacy for social transition, access to care and services, and resources for social and legal transition supports as available

Pre-pubescent patients who are interested in future puberty suppression should be seen initially every three to six months by their medical provider for supportive and affirming care, patient and family education, and on-going assessment of appropriateness of care and to assess Tanner staging and other needs as indicated. Frequency of visits may increase after Tanner stage 2 and initiation of GnRH agonists. Visits prior to medical gender affirmation treatment supports the development of patient and provider rapport and trust, provides a space for continued education, and promotes the growth of robust supports to reduce stress over the course of treatment for gender affirmation.

03. Puberty Suppression and/or Gender Affirming Hormone Therapy (GAHT)

A complete medical assessment, as described above, must be documented in the chart before initiating any medical treatment for puberty suppression and/or GAHT. This includes documentation of informed consent signed by all parents/legal guardians as well as an indication of the patient's assent to care. During this process of consent, the medical provider should review realistic expectations of puberty suppression and/or GAHT. Review must include the short and long-term effects these medications may have, including desired effects that may not be possible or realistic. Medication benefits and risks will be explained, as well as unknowns about potential long-term health risks or complications. The medical provider will have a conversation with the patient and their family about future fertility and, as appropriate, assess the patient's future fertility goals in language and context that is age-appropriate. Finally, patients should be encouraged to complete a behavioral health assessment and engage in therapeutic support before and during gender affirming medical treatment.

The medical provider may waive behavioral health service requirements after a medical evaluation and in circumstances where an appropriate MHP is not accessible due to finances or distance. This requirement may also be waived when a youth has presented with significant maturity, family and social supports, and when it is determined that insistence on a behavioral health assessment may cause more stress or harm than benefit. In these rare cases of deferment of the behavioral health assessment, medical providers are strongly encouraged to discuss the patient's case with the TYCT/TCT prior to initiation of any puberty

suppression and/or GAHT in order to review the recommendation to forego a behavioral health assessment prior to medical treatment for gender affirmation.

See Appendix B for consent forms

Puberty Suppression Treatment

Patients who are Tanner 1 should be assessed medically every 6 months to determine their ongoing pubertal development with an increase in frequency to every 3 months when pubertal development is expected in order to capture Tanner 2 developmental staging as it occurs.

Puberty suppression may be started at Tanner stage 2 to 3. Puberty suppression at Tanner 4-5 may also be appropriate based on the individual patient's degree of development of secondary sex characteristics and/or the patient's and/or family's readiness to initiate GAHT.

Patients and families should be advised that within the first 1-2 weeks after initiation of GnRH agonists, there will be an initial surge of FSH, LH, and subsequently endogenous sex hormones (estrogen or testosterone) as the agonist (medication) binds to GnRH receptors, which may briefly accelerate puberty. Once the receptors are saturated, FSH and LH — and subsequently testosterone or estrogen — will be down regulated and suppressed, and the pubertal process blocked. This initial surge may cause some patients to experience short, but intense symptoms of puberty (onset of menses, brief growth spurt, breast tenderness) that might trigger dysphoria and distress.

For youth who have already progressed through the early stages of puberty and are Tanner Stage 4 or 5, the use of GnRH analogs — and the initial suppression of testosterone or estrogen — may cause symptoms mimicking acute onset of menopause or hypogonadism as the medication blocks the pubertal sex hormones. This sudden drop in endogenous sex hormone may cause symptoms such as hot flashes, headaches, fatigue, irritability, flattening of mood, and/or worsening depression or anxiety. Patients and their families should be made aware of these potential effects, and it is strongly encouraged that patients be supported medically and emotionally through this process.

Medical providers will work with the pharmacy and medical team staff to get insurance authorization for use of GnRH agonists for the patient when necessary.

Initiating puberty suppression

Treatment with GnRH Agonist *(See further treatment adjustments under labs below)*

- Leuprolide given IM every 28 days
 - Start at 7.5mg-11.25mg dose if weight \leq 25kg

- Start 11.25mg-22.5mg if weight > 25kg
- Luprolide Acetate 3 month Pedi-Depot given IM every 12 weeks
 - Start 11.25mg-22.5mg
- Histrelin acetate subcutaneous implant 50mg inserted every 12 months

If GnRH agonists are not available

Youth assigned female sex at birth (AFAB)

- Consider Depo-Provera 150mg IM every 12 weeks for suppression of menses

Youth assigned male sex at birth (AMAB)

- Consider spironolactone 25mg to 300mg daily for suppression of testosterone

Follow up visits

For those on GnRH agonist, follow-up should occur one month after initiation of treatments and move to every 3 months as indicated by response to medication

- Assess for satisfaction with and side effects of medication
- Assess mental health and presence of and impact from any social stressors
- Inquire about progress of social gender affirmation
- Document growth: height and weight, Tanner staging

Labs with every 3-month follow up visits

- Serum estradiol or testosterone, and FSH, LH (should be suppressed to pre-pubertal levels), liver function;
 - Adjust dosing of GnRH analogue if elevated testosterone/estradiol, FSH/LH or clinical evidence of pubertal development
 - If administering Leuprolide every 28 days:
 - Increase by 3.75mg as often as every 4 weeks to desired clinical response
 - If administering Leuprolide acetate 3-month pedi depot injections every 12 weeks:
 - increase to 22.5mg or 30mg, or shorten interval between injections to desired clinical response

- If using spironolactone, consider increasing by 25mg to 50mg a day until desired clinical effect (suppression of testosterone).

Annual Labs once stabilized on treatment

- Serum estradiol or testosterone, and FSH, LH (should be suppressed to pre-pubertal levels)
- Renal and liver function, Alk phos, Calcium, vitamin D
- Lipids, glucose and/or Hgb A1C, prolactin only as indicated based on individual risk factors or symptom development
- Yearly bone age (left hand radiograph), if concerns about height development if indicated by patient risk and medical history
- Yearly bone densitometry, if at risk for baseline osteoporosis or use of GnRH analogues for more than 2 years
 - Coordinate with outside specialists to manage any bone density conditions
- Consider other labs and/or referral to endocrinology in relation to additional risk factors, height goals, or symptom development

Initiating GAHT with puberty suppression treatment

Criteria to initiate GAHT

- Age appropriate to the development of the desired secondary sexual characteristics in the same age cis-gender cohort:
 - 14.5 to 15 years of age for trans boys AFAB
 - 13 to 14 years of age for trans girls AMAB
- Persistent, stable and well-documented gender identity (6+ months per *DSM-5* criteria)(10)
- Stable and adequately managed mental health and medical conditions [11]
- Pubertal suppression is judged to be enough to have allowed the patient to integrate their gender more fully, to provide adequate time for assessment and evaluation of the level and impact of gender incongruence and the role of medically necessary gender affirmation treatments to relieve symptoms of gender dysphoria. The duration of pubertal suppression prior to initiating GAHT will be based on patient response, lab monitoring, monitoring of growth parameters, as well as an assessment of bio-psycho-social concerns in relation to age-matched peers.

- And/or Unacceptable height development in trans-female AMAB patients
 - Consider referral to endocrinology for trans masculine AFAB patients when there is indication for use of growth hormones to achieve more typical male height ranges
 - Consider earlier initiation of GAHT in trans feminine AMAB patients (age 13+) to assist in closing the growth plates for more typical female height ranges
- No medical contraindications to GAHT
- Discussion of risks, benefits and course of treatment using standard consent forms for GAHT (see *Appendix B*)
- Discussion with patient and parents/guardians demonstrating their understanding of potential permanent risks to fertility
- Discussion with patient and parents/guardians demonstrating their understanding of risks and benefits of GAHT including willingness to continue regular follow up appointments and patient's agreement to take medication as prescribed
- Signed consent for use of GAHT by all parents/guardians with signed assent of patient.

GnRH analogue may be continued until adult doses of GAHT are achieved. Consider continuing into late adolescence/early adulthood.

Initiating GAHT post-pubertal (Tanner stage 5)

Criteria to initiate GAHT without puberty suppression

- Age appropriate to the development of the desired secondary sexual characteristics in the same age cisgender cohort:
 - 14.5 to 15 years of age for trans boys AFAB
 - 13 to 14 years of age for trans girls AMAB
- Complete behavioral health and medical assessment as described above.
- Persistent, stable and well-documented gender identity (6+ months per *DSM-5* criteria) [10]
- Stable and adequately managed mental health and medical conditions [11]
- No medical contraindications to GAHT
- Discussion of risks, benefits and course of treatment using standard consent forms for GAHT (see *Appendix B*)

- Discussion with patient and parents/guardians demonstrating their understanding of potential permanent risks to fertility
- Discussion with patient and parents/guardians demonstrating their understanding of risks and benefits of GAHT including willingness to continue regular follow up appointments and patient's agreement to take medication as prescribed
- Signed consent for use of GAHT by all parents/guardians with signed assent of patient.

04. Gender Affirming Hormone Therapy Medications

Initiate treatment at higher doses of hormone if not using GnRH analogue.

Masculinizing GAHT

Injectable testosterone cypionate (suspension in cottonseed oil) is the more common initial choice in the U.S. Providers may shift to testosterone enanthate (suspension in sesame seed oil) if patient develops itching and hives at injection site. Available in 100mg/mL and 200mg/mL. Choice of concentration depends on the volume of dose and ease of syringe use.

IF Injectable testosterone subcutaneous (SC), or intramuscular (IM)

- Start at 12.5mg to 25mg weekly
- Increase dose by 12.5mg every 3 to 6 months to an adult dose of 50mg to 100mg weekly (100-200mg biweekly).

Speed and degree of dosing adjustment is based on age of patient, clinical response, and serum testosterone levels. Adult goal total testosterone ranges vary widely. Goal should be in the normal physiologic cisgender male range (320 to 1000 ng/dL). [7]

Blood levels are usually checked at mid cycle, but may be checked at peak and trough as appropriate to find range of levels that may be associated with shifts in patient experiences.

(See Appendix C for recommended labs tables)

It is not recommended to use topical/transdermal testosterone until an adult dose has been achieved unless patient experiences needle phobia and/or inability to tolerate injections.

Feminizing GAHT

IF transdermal estradiol patch

- Apply twice weekly starting at dose of 6.25mcg (1/4 of a 25mcg patch) to 25mcg

- Increase dose every 3 to 6 months to adult doses of 200mcg to 400mcg

IF daily sublingual estradiol tablets

- Start at 0.25-0.5mg
- Increase dose every 3 to 6 months to adult doses of 4mg to 6mg daily

There are data that suggest sublingual dissolving of estradiol tablets results in a spike in estrogen blood levels a few hours of taking the medication. This response is not shown with ingestion of pills. This difference may affect lab values or individual patient's experiences of highs and lows of hormone levels daily. [12]

IF injectable estradiol valerate

- Start 5mg IM every other week
- Increase every 3 to 6 months to adult doses of 10mg to 40mg every other week

Be aware that in the US there are frequent shortages of injected estrogen that may require switching formulations used by patients and may cause the patients significant distress.

IF injectable estradiol cypionate

- Start 2mg IM weekly
- Increase every 3-6 months to adult doses of 10mg weekly

Be aware that in the US there are frequent shortages of injected estrogen that may require switching formulations used by patients and may cause the patients significant distress.

Androgen blockade in transfeminine patients not using GnRH analogue

IF Spironolactone

- Start at 50mg daily on days 1 to 7 then 50mg twice daily on days 8 to 14 then 100mg twice daily after day 14.

IF finasteride

- 5mg daily if contraindications to, or lack of tolerance of spironolactone.

05. Follow Up for All Patients Receiving GAHT

- Every 3 months during the first year of GAHT.
- Every 6 months for the next 2 to 4 years.
- Annually after 4 years and as patient transitions into adult care.

At each appointment

- Assess for satisfaction with and GAHT
- Assess mental health and any changes
- Assess stressors and plans related to social gender affirmation
- Assess growth milestones: height and weight. (see: *Appendix D*)
- Assess Tanner staging for children who have been on puberty suppression until reaching Tanner 5.

Labs to Check

Transfeminine patients

At 4-6 weeks

- If on spironolactone, check serum potassium and BUN/Creatinine. Thereafter check 4-6 weeks after dose changes of spironolactone.

At 6 months

- Estradiol level goal between 100-200pg/mL. #Endocrine society guidelines
- Serum total testosterone
 - Goal is to suppress testosterone into the normal female range (5-<50 ng/dL) [7]
 - Serum potassium, BUN/Creatinine

Annual labs after stable dose and serum concentration is attained:

- Serum potassium, BUN/Creatinine, estradiol, total testosterone
 - Prolactin (more frequently if symptoms suggest hyperprolactinemia or pituitary adenoma)
- Lipid profile, glucose, Hemoglobin A1c only as clinically indicated and/or as current guidelines suggest

Transmasculine patients

At 3-6 months

- Testosterone levels every 3-6 months until dose and levels are stable. Goal: total testosterone 320 to 1000 ng/dL.
- Hematocrit [1]

At 12 months

- Serum T

- Total testosterone
- Hematocrit
- Lipid profile

Annual labs after stable dose and serum concentration is attained:

- Hematocrit yearly
- Serum total testosterone does not need to be monitored yearly in patients on stable doses. Consider checking in patients with potential side effects, abnormal genital bleeding, or inadequate/unsatisfactory masculinization
- Lipids should be monitored based on current USPSTF guidelines for males, with regard to personal risk factors and family history
- Glucose and A1c monitoring may be considered for patients with presumed higher risk of diabetes (including PCOS, obesity, family history)

06. Patients seeking gender confirming surgery

As patients approach 18 years of age, or if initiated by patient prior, it may be appropriate to discuss and assess any desires or needs for surgical gender confirmation procedures. Refer patients seeking surgical gender confirmation to Fenway or external MHP for surgical assessment and referrals as appropriate. Coordinate referrals to surgeons as needed and appropriate and provide follow up pre/peri/post-operative care as needed. Medical providers may need to assist patient to arrange specialist care peri-and post-operatively to provide on-going support for healing and/or management of any complications that might arise. [13]

A patient may experience significant distress due to barriers to surgical affirmation including lack of services in the area and financial inaccessibility. Providers should continue to assess the need for continued/further supports and resources to assist with gender affirmation, such as non-surgical gender affirmation options as appropriate (i.e., binders, packers, tucking, documents, voice therapy, etc.).

07. Additional Supports

When appropriate, the medical team, including the medical case manager and behavioral health specialist should offer assistance with social gender affirmation/changes in name and sex designation on legal documents that may require a physician's attestation to amend. (Templated letters for change of sex on passports and Social Security are in the **Fenway** electronic health record.)

If the medical team is unable to assist with the needs of a gender diverse patient, supports to locate additional resources and referral information may be available through the Trans Health Patient Advocate at Fenway and/or local or state resources.

Consider legal referral for issues around guardianship and parental consent or in situations where discrimination is occurring in school, at work, or home, and when there are barriers to access of medically necessary care. Legal supports and information may be available to patients through GLAD.org and Massachusetts Transgender Political Coalition (MassTPC.org), amongst other local and national legal organizations. Patients should be referred to the Fenway Violence Recovery Program for any concerns regarding discrimination, abuse, or violence they may be facing, including issues of immigration or asylum.

09. Youth in DCF Custody

Clinicians must work closely with a youth's DCF caseworker at every step of gender affirmation treatment for a youth in custody. The DCF caseworker has limited ability to approve some aspects of treatment, such as lab work and consenting to medical records release of information. DCF caseworkers cannot consent to a youth's GAHT and/or GnRH agonist treatment on their own authority. DCF must petition the Court on behalf of the youth for authority to approve GnRH agonist and/or GAHT treatment.

Ideally, the medical provider should notify the DCF caseworker immediately when a minor in custody presents to Fenway's Medical or Behavioral Health Departments requesting assessment for gender affirming care. The DCF caseworker should be encouraged to start the process for a court petition as soon as possible due to anticipated delays in the court system, which may hold up the youth's progress and potentially lead to and/or worsen their distress.

The DCF caseworker assigned to the youth will help coordinate the process for consent by the Court for the use of GnRH agonists and/or GAHT. The Court will appoint a Guardian Ad Litem (GAL) to represent the youth's interests and to coordinate testimony, affidavits, and subpoenas relevant to the court approval process. Medical and behavioral health clinicians working with youth in DCF custody may be asked to submit affidavits to the court explaining the process by which the minor is assessed for treatment and may be subpoenaed to attend court hearings where judges review the appropriateness of treatment. In court hearings DCF is represented by legal counsel; the youth is represented by their GAL and their legal counsel. Parents or other family members may have separate legal counsel present in situations where family members retain some limited rights.

Court approval for the use of GAHT and/or GnRH agonist treatment may require sequential approval for changes in dosing/medications, as well as requiring

regular update reports to the court and/or the GAL. The medical provider is responsible for working closely with the DCF caseworker and GAL to meet these requirements.

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Appendix A: Letter to Request Youth GAHT Assessment and Referral Report

Dear Mental Health Professional:

You have received this form to assist you in preparing to refer a client in your practice to Fenway Health for consideration for gender affirming hormone therapy.

Hormone therapy may be initiated with patients under the age of 18, if medically appropriate, with a referral from a qualified mental health provider, or a health professional with behavioral health training in assessment of gender dysphoria. The referral needs to provide documentation of the client's personal and treatment history, progress, and eligibility for hormone treatment. This includes documentation of any co-existing mental health, medical, or substance use concerns and how these are being addressed or managed, as well as documenting the support of the person's parents/guardians for this medical treatment. Medical clearance is managed separately through the individual's medical provider.

For patients under age 18, we require a report on the readiness of the patient's family or system of supports, in addition to the report of the full bio-psycho-social assessment of the patient related to their experience of gender incongruence. The letter needs to establish clearly the presence of gender dysphoria and the likely outcome anticipated from gender affirming medical treatments on this condition. The content areas are outlined below and we request that you specifically address these within your mental health referral letter.

Thank you for referring your client to us to assist in such important care. Contact the patient's medical care provider or care team at the location of their care listed below if you have any questions.

Thank you.

Fenway Health Trans Health Program

<https://www.fenwayhealth.org/transhealth>

transhealth@fenwayhealth.org

Enc. GAHT Youth Evaluation Information Outline

Gender Affirming Hormone Therapy Youth Evaluation Outline

Please address each of the following areas in a letter.

If an area is not applicable, please indicate this in your letter.

Letters may be mailed or faxed. (See attached list of fax numbers).

Include a clear statement of whether you recommend this person begin hormone therapy.

1. Demographic Information

- Name used, legal name if different, and date of birth.
- Length of time you have seen this client and type treatment.
- Focus of treatment.
- Client's current gender presentation including the any/amount of time living openly in the affirmed gender during an average day and any efforts and actions to present in a more gender congruent manner. If not full-time, indicate to what extent the person lives in their asserted gender identity and what obstacles inhibit full-time expression of their gender identity.
- Describe the family/guardian, peer, school, and other social support systems and how these interact with the person, particularly around the person's asserted gender. Describe all supports and any lack of supports around the youth's gender identity and expression and how the person is coping with this situation.

2. Brief Gender History (Summarize pertinent information related to gender identity development, milestones, challenges, and relationship history, etc. where known or present. Please note any areas not explored with the person.)

- During Childhood.
- During Puberty or concerns with Anticipated Puberty.
- Dating/Relationship history or absence of, as appropriate.
- Sexuality or absence of same (e.g., milestones and development esp. as it relates to gender identity and expression and/or trauma and abuse), as appropriate.

3. Substance Use/Abuse

- Current use/abuse (*this must include mention of tobacco use, alcohol, and marijuana at a minimum even if there is no use history of these substances*)
- History of use/abuse and all substance/alcohol treatment

4. Mental Health & Medical Health History

- Any co-occurring medical and/or mental health diagnoses; abuse, assault, violence, or discrimination history. Concerns affecting gender identity and how these are being addressed or have been resolved and person's current coping skills and patterns. (Provide ICD-10

diagnoses, list all medications and over the counter drugs, vitamins, etc. List all other known health care providers and their contact information).

- Current risk assessment.
- Past risk history (treatment, hospitalizations w/ dates, precipitating causes, outcome, and facility/clinic name and location).
- Describe the person’s understanding of potential outcomes (risks and benefits) of hormone treatment. Include a report of how they imagine the hormone treatments may change their lives.
 - You must report on conversations with and understanding by the person and their parents/guardians on reproductive rights and potential issues from hormone treatment.

5. Additional Information

- Include any other relevant information that was not included above including whether the person is or has ever been on hormone therapy whether medically prescribed, ‘do-it yourself,’ or herbal hormone remedies.
- Include your name, professional licensure level, and contact information. State whether the person intends to continue seeing you for mental health supports after this referral is complete.

Locations: (Please select the location where your client receives care to mail the referral letter or to contact the location for the fax number for their provider.)

Fenway Health, Ansin Bldg.
 1340 Boylston St., Boston, MA 02215
 617-927-6000

Fenway: South End
 142 Berkeley St., Boston, MA 02216
 617-247-7555

Sidney Borum, Jr. Health
 75 Kneeland St., Boston, MA 02111
 617-457-8140

Appendix B: Informed Consent Forms

Informed Consent for Masculinizing Hormone Therapy

For _____ Date of Birth: _____ Name Used: _____
Patient Name as listed in chart Name if different from chart

This form will assist you (and your guardian) to think through the expected effects of hormone therapy including possible unwanted side effects. You are encouraged to talk about this treatment with your medical provider and decide if hormone therapy is right for you (your child). By signing this form, you are stating that you have discussed the effects and risks of this medication with your medical provider or a member of the medical team and that you understand and accept these effects and possible risks. You (and your guardian) may ask questions and talk about any concerns you have related to this treatment at any time in this process.

Testosterone is used to masculinize the body (make it look more traditionally male). This medical treatment will reduce some female features and increase male features. Your medical provider will help decide which form of testosterone (injectables, gels or creams, patches, implanted pellets) and the amount that is best for you based on your personal needs and any medical or mental health conditions you might have. Each person’s body responds to testosterone differently and it is hard to promise or predict with certainty how each person may respond to treatment. Your medical provider will talk with you throughout the treatment and will help you achieve the best results safely. As part of this treatment, you agree to take the testosterone only as prescribed and to talk with your medical provider before making any changes in your medication dose.

Many years of experience in treating gender diverse people and accepted, published medical guidelines on hormone treatment inform the use of hormone therapy for gender confirmation/affirmation (transition) in this health center. Continuing research on hormone therapy provides us with more information on the safety and usefulness of hormone therapy to relieve gender dysphoria or incongruence when appropriate. Nonetheless, medicine does not fully understand the long-term effects of testosterone therapy across the lifespan.

Read the following information and initial each section where indicated once you are sure you (your guardian) understand the information and your questions have been answered to your satisfaction.

Expected Effects of Testosterone Therapy

The masculinizing changes in your body may take several months to become noticeable and usually take 3 to 5 years to be complete.

Some changes are PERMANENT; they will not go away or go back to the way your body looked before treatment, even if you decide to stop taking testosterone or take a lower amount:

- The pitch (sound) of your voice will deepen

- Growth, thickening, and darkening of hair on the body increases to look more like men in your family
- Growth of facial hair - beard and mustache - will usually look like men in your family
- Possible hair loss at the temples and crown/top of the head (male pattern baldness) with possible complete baldness [Usually this looks like the hair patterns of men in your family and is a genetic feature inherited from your parents.]
- Growth in the size of the clitoris/phallus

Some changes are NOT PERMANENT; they will likely go away or go back to how your body looked or worked before treatment if you stop taking testosterone after a few weeks to months or longer depending on the change:

- Menstrual/monthly periods (bleeding) stop, usually within a few months of starting testosterone. There may be changes to the inside lining of the vagina (thinning, dryness) that may lead to increased risks of injury or infections if you are sexually active and may make routine genital screening exams more difficult.
- Changes in where fat is stored in the body: If you gain weight, the fat will tend to go to the stomach and mid-section, rather than the buttocks, hips and thighs. You may lose fat from breasts, buttocks, and thighs if you lose weight.
- Muscle mass and upper body strength increase.
- Some people feel more energy, more active, or more short-tempered and angry. Some people experience improvement in their mental health; they feel better or calmer and more focused.
- Many people experience skin changes including a lot of acne on the face and back that may need medical treatment to manage. This may last for months to a few years like in puberty.
- Most people experience a big increase in their sex drive or interest in sexual activity. Some people experience changes in who they are attracted to physically.

_____ (initials) My (my child's) medical provider or member of the medical team has answered my questions about the effects of testosterone. _____
 (initials) Provider _____ Date discussed _____

Possible Side Effects and Risks of Testosterone Therapy

- Possible loss of fertility; you may not be able to get pregnant after being on testosterone therapy for some time; how long this might take to be a permanent effect is unknown. Some persons choose to harvest and bank eggs before starting testosterone.
- Testosterone is not reliable birth control. Even if menstrual periods (bleeding) stop, you could get pregnant; if you are having genital sex with a partner who produces sperm, discuss with your medical provider using some form of birth control
- *If you get pregnant while taking testosterone, the high levels of testosterone in your system may cause harm and even death to the developing fetus.*
- Other effects of testosterone on the ovaries and on ova (eggs) are not fully known
- Some trans masculine people, after being on testosterone for a number of months, may develop pelvic pain. Some experience this pain with sexual arousal and orgasm and some for no apparent reason. The level of pain varies in the people who experience this effect. For some the pain goes away after some time. For others the

pain may persist. For a few the pain seems to go away only with removal of the uterus (hysterectomy). The cause of this pain is unknown.

- The cervix and walls of the vagina may become drier and more fragile (thinner). This may cause irritation and discomfort. It also may make you more vulnerable to sexually transmitted infections and HIV if you have unprotected sex using the vaginal opening (front hole).
- Testosterone will not protect against cervical, ovarian, uterine, or breast cancer. Regular cancer screening recommendations continue, even after top surgery and chest reconstruction, including regular pap tests as appropriate until or unless removal of the uterus and cervix. Current research indicates there may be no increased risk for these cancers above the risks already present for any individual based on medical conditions and genetics.
- Possible worsening of cholesterol, increased blood pressure, and other changes to the body may also increase risk of cardiovascular disease (heart attacks, strokes and blockages in the arteries) when on testosterone therapy long-term. The risks for heart disease for trans-masculine people taking testosterone are like the risks that are found in non-transgender (cisgender) men and will generally reflect the genetic risk for heart disease among the men in your family.
- Possible changes in the body that might increase the risk of developing diabetes.
- Increased appetite is common and may result in weight gain of both muscle and fat
- Increased risk of sleep apnea (breathing problems while you are sleeping) appears related to testosterone treatment.
- Possible abnormalities in blood tests for the liver; possible worsening of damage to the liver from other causes. The liver will be monitored in annual exams or as needed.
- Possible increase in the hemoglobin and hematocrit (the number of red blood cells). If this increases to levels higher than is normal in males, it may cause problems with circulation, such as blood clots, strokes and heart attacks
- Increased sweating when exercising and when sleeping.
- Weakening of tendons and increased risk of injury to them.
- Possible worsening or triggering of headaches and migraines.
- Possible increase in frustration, irritability or anger; possible increased aggression and worsened impulse control.
- Possible worsening of bipolar disorder, schizophrenia and psychotic disorders or mood disorders.
- Possible changes in brain structure and functioning are unknown over long-term treatment with testosterone. Some limited research suggests a decrease in verbal fluency (talkativeness or using lots of words).

_____ (initials) My (my child's) medical provider or member of the medical team has answered my questions about the risks of testosterone. _____ Provider
 _____ Date discussed

_____ (initials) I (patient/guardian) understand that testosterone is not a form of birth control and that even if my monthly periods (bleeding) stop, I could still ovulate and get pregnant if I have sexual activity that could result in pregnancy. _____
 Provider _____ Date discussed

_____ (initials) I (patient/guardian) understand that if I stop testosterone in the

*future, I may not be able to get pregnant even if I want to. I have discussed options for egg banking with my medical provider or member of the medical team who has answered my questions about fertility preservation. _____ Provider
_____ Date discussed*

You understand

- Smoking cigarettes may increase some of the risks of taking testosterone therapy
- Taking testosterone in doses that are higher than recommended will increase any risks from testosterone. Higher doses than prescribed will not work better or faster to masculinize the body. The body may convert (aromatize) high amounts of testosterone to estrogen through the fat in the body. This conversion of extra testosterone to estrogen may interfere with masculinization or may cause other problems.
- Testosterone therapy is typically lifelong. Suddenly stopping testosterone after a long time on the medication may have negative physical and mental health effects.
- You may choose to stop hormone therapy at any time and for any reason. You are encouraged to discuss this decision with your medical provider prior to making any changes in your medication.
- Your provider may decrease the dose of testosterone or stop prescribing testosterone because of medical reasons and/or safety concerns. You can expect the medical provider to discuss the reasons for all treatment decisions with you (and your guardian).
- Hormone therapy is not the only way that a person may appear more masculine/male in their lives. Your medical provider and/or a mental health provider are able to talk with you about other options if you are interested.

*_____ I would like to discuss ways to help me quit smoking
_____ (initials) I (my child and I) understand these risks and expectations of taking testosterone. _____ Provider _____ Date discussed*

You agree to (Responsibilities)

- Take testosterone only at the dosage and in the form that your medical provider prescribes.
- Inform your medical provider if you are taking or start taking any other prescription drugs, dietary supplements, herbal or homeopathic drugs, street/recreational drugs, or alcohol. Being honest about what I am taking/using will help my medical provider prevent or reduce potentially harmful reactions or interactions.
- Inform your medical provider of any new physical or emotional symptoms and any medical conditions that develop before or while you are taking testosterone. *Inform your provider if you think you are having bad side effects from the testosterone.*
- Keep regular follow up appointments; this may include appointments for Pap tests, pelvic exams, and mammograms (cancer screenings) as indicated by my medical situation.

- Have regular blood testing done to monitor your health and hormone treatment. Your medical provider will discuss with you what tests are necessary and what the tests will do to help keep your care the best it can be.
- I agree that if I have any condition that may cause me harm if I start or continue taking testosterone, I will work with my medical provider to evaluate and treat the condition before starting or continuing testosterone therapy.
- I understand that I can choose to stop testosterone at any time after making a plan to stop the treatment with my medical provider. I understand that my provider may stop my testosterone treatment at any time if it is necessary for my medical/clinical safety.

_____ (initials) My (my child's) medical provider or member of the medical team has answered my questions about these rights and responsibilities while taking masculinizing hormone therapy. _____ Provider _____ Date discussed

By signing this form, you acknowledge that you and/or your legal guardian(s) have adequate information and knowledge to be able to make an informed decision about hormone therapy and that you understand the information your medical provider has given you. Based on this information (choose one):

I _____, _____ choose to start testosterone
Patient's name listed on insurance or chart

—OR— _____ do not want to start testosterone to masculinize my body.

 Patient signature (name in chart) Date

 Patient's Date of Birth

 Patient's name used, if different from chart

 Parent/Guardian signature (1) Date

 Parent/Guardian Signature (2) Date

 Parent/Guardian signature (1) PRINTED

 Parent/Guardian Signature (2) PRINTED

 Provider signature Date

 Provider name PRINTED

If I choose (choose for my child) to start testosterone therapy, I agree to have (to bring my child for) regular physical examinations and blood tests to make sure that I am (my child is) not having a bad reaction to testosterone. I understand that this is required to continue testosterone therapy at this clinic.

_____ (initials) Patient/guardian _____ Provider _____ Date

Informed Consent for Feminizing Hormone Therapy

For _____ Date of Birth: _____ Name Used: _____
Patient Name as listed in chart Name if different from chart

This form will assist you (and your guardian) to think through the expected effects of hormone therapy including possible unwanted side effects. You are encouraged to talk about this treatment with your medical provider and decide if hormone therapy is right for you (your child). By signing this form, you are stating that you have discussed the effects and risks of this medication with your medical provider or a member of the medical team and that you understand and accept these effects and possible risks. You (and your guardian) may ask questions and talk about any concerns you have related to this treatment at any time in this process.

Estrogen (usually estradiol) is used to feminize the body (make it look more traditionally female). This medical treatment will reduce some male features and increase some female features of the body. Androgen (testosterone) blockers further decrease the amount of and/or block the effect of testosterone and masculinization of the body. Your medical provider will help decide which form and the amount of estrogen (injectables, pills, gels, patches) and androgen blockers (pills, gels, shots, implanted) that are best for you based on your personal needs and any medical or mental health conditions you might have.

Each person's body responds to estrogen differently and it is hard to promise or predict with certainty how each person may respond to treatment. Your medical provider will talk with you throughout the treatment and will help you achieve the best results safely. As part of this treatment, you agree to take the estrogen only as prescribed and to talk with your medical provider before making any changes in your medication dose.

Hormone therapy will not change some male/masculine features. A person's bone structure or height will not change. The Adam's apple will not shrink. The pitch of the voice will not automatically change. If necessary and appropriate, other treatments in addition to hormone therapy are available to help with these things.

Many years of experience in treating gender diverse people and accepted, published medical guidelines on hormone treatment inform the use of hormone therapy for gender confirmation/affirmation (transition) in this health center. Continuing research on hormone therapy provides us with more information on the safety and usefulness of hormone therapy to relieve gender dysphoria or incongruence when appropriate. Nonetheless, medicine does not fully understand the long-term effects of estrogen therapy across the lifespan.

Read the following information and initial each section where indicated once you are sure you (your guardian) understand the information and your questions have been answered to your satisfaction.

The Expected Effects of Feminizing Hormone Therapy

The feminine changes in the body may take several months to become noticeable and usually take up to 3 to 5 years to be complete.

Changes from taking estrogen that will be PERMANENT; they will not go away or go back to the way your body looked before treatment, even if you decide to stop taking estrogen or take a lower amount:

- Breast growth and development. Breast size varies across all women. Some of this is genetic and somewhat predictable based on the size of the breasts of a mother, sisters, or aunts. Breasts may look smaller on a broad chest. If you stop taking estrogen your breasts may shrink some but will not go away completely.

_____ (initials) My (my child's) medical provider or member of the medical team has answered my questions about the effects of estrogen. _____ (initials)
 Provider _____ Date discussed _____

Changes that are NOT PERMANENT and will likely return to the way your body looked or worked before treatment with estrogen:

- The testicles will get smaller, softer, and will produce less sperm
- The ability to get someone pregnant may decrease significantly or stop (infertility). The time this takes and whether infertility becomes permanent varies greatly from person to person. Fertility may or may not return after stopping estrogen.
- Loss of muscle mass and decreased strength, particularly in the upper body
- Decreased metabolism and weight gain. If you gain weight, the fat will tend to increase in the buttocks, hips, and thighs in a more typically feminine/female body pattern.
- Skin may become softer and existing acne may decrease
- Facial and body hair will get softer and lighter and grow more slowly, but will not go away
- Male pattern baldness on the scalp may slow down or stop, but hair may not regrow
- Sex drive may decrease from a little to a significant amount
- Decreased strength of erections or inability to get an erection. The ejaculate will become thinner and watery and there will be less of it.
- Changes in mood or thinking may occur; some people may feel increased emotional reactions and others may feel more balanced or less emotional.

_____ (initials) My (my child's) medical provider or member of the medical team has answered my questions about the effects of estrogen. _____ (initials)
 Provider _____ Date discussed _____

Risks and Possible Side Effects of Estrogen Therapy

- Brain structures respond differently to testosterone and estrogen and current medical science does not fully understand these responses. Taking estrogen therapy may have long-term effects on the functioning or structure of the brain that are impossible to predict.
- Loss of fertility (unable to get someone pregnant). Even after stopping hormone therapy, may not come back. How long and whether this becomes permanent is difficult to predict. Some people choose to bank some of their sperm before starting hormone therapy.
- Possible increased risk of developing blood clots. Risks are uncertain overall, with higher risks in those with a family or personal risk of blood clots, and

those using high doses of or some forms of estrogen (i.e., Premarin). Other research shows lower risks with other forms of estrogen (patches). Additional increased risks occur if you smoke, are exposed to, or use tobacco while taking estrogen therapy. Risks include developing blood clots in the legs or arms (DVT); blood clots in the lungs (pulmonary embolus); blood clots in the arteries, including the arteries of the brain. Blood clots to the lungs, heart, or brain could result in death.

- Possible increased risk of developing cardiovascular disease, a heart attack, or stroke. This risk may be higher if you use tobacco products, are over age 45, or already have high blood pressure, high cholesterol, diabetes, or a family history of cardiovascular disease, and if you have low physical activity.
- Possible increase in blood pressure requiring treatment with medication.
- Possible increased risk of developing diabetes. Limited research found an increase in insulin resistance in trans-feminine people taking estrogen therapy. The effect of hormone therapy on the risks of developing or management of diabetes remains unclear.
- Possible nausea and vomiting, especially when starting on estrogen therapy
- Possible increased risk of gallbladder disease and gallstones
- Estrogen may lead to liver inflammation and/or contribute to existing liver damage
- May cause or worsen headaches and migraines. Migraine headaches have a clear hormonal element. Estrogen may increase the intensity or frequency of migraines.
- May cause elevated levels of prolactin (a hormone made by the pituitary gland); a few persons on estrogen for hormone therapy have developed prolactinomas, a benign tumor of the pituitary gland that can cause headaches and problems with vision and cause other hormone problems
- The effect of starting estrogen therapy on mental health conditions is unknown. Some people may feel their mental health and social comfort increases and others may feel it declines. There is no clear evidence that estrogen therapy is directly responsible for causing or making worse any mental health conditions. If you have a history of depression, anxiety, or other mental health diagnoses, discuss these with the clinic staff to explore modifications to hormone therapy and other supports and services are best to meet your needs.
- Risks of breast cancer are unclear. The risk may be higher than in non-transgender men and lower than in non-transgender women. Risk factors include family and genetic history of breast cancer, length of time on estrogen therapy, age when starting estrogen therapy, and exposure to progesterone.

_____ (initials) My (my child's) medical provider or member of the medical team has answered my questions about the effects of estrogen. _____ (initials)
 Provider _____ Date discussed _____

Risks and Possible Side Effects of Androgen Blockers (Spironolactone)

- Increased urine production and needing to urinate (i.e., pee) more frequently; possible changes in kidney function
- A drop in blood pressure and feeling lightheaded, especially when standing up from sitting or lying down

- Increased thirst
- Increase in the potassium in the blood and in your body; this can lead to muscle weakness, nerve problems and dangerous heart arrhythmias (irregular heart rhythm)
- If used without estrogen therapy, androgen blockers may cause hot flashes and low mood or energy.
- Long-term use of androgen blockers to block fully testosterone without additional hormone therapy may result in bone loss.

_____ (initials) My (my child's) medical provider or member of the medical team has answered my questions about the effects of androgen blockers. _____
 (initials) Provider _____ Date discussed _____

You understand that

- Smoking, inhaling second-hand smoke, and use of tobacco products may greatly increase the risks of taking feminizing hormone therapy, especially the risk of blood clots and cardiovascular disease. If you smoke or use tobacco products, you should work to cut down or quit. Your provider may ask you to quit smoking before you start on hormone therapy.

_____ I would like to discuss ways to help me quit smoking or use of tobacco products.

- Estrogen therapy may not prevent unplanned pregnancy. Estrogen therapy is not a method of birth control. There is no way to predict when or if a person will become infertile (unable to get someone pregnant) when taking hormone therapy. Other birth control methods will be necessary (condoms, oral contraceptives, etc.) to prevent pregnancy if you are having any type sex that could result in a pregnancy.
- Estrogen therapy will not prevent you or anyone from getting or passing on HIV or any sexually transmitted illness.
- Taking estrogen in doses that are higher than recommended by your doctor will increase your risk of side effects and does not produce better or faster feminizing effects.
- If you want or need surgery in the future, you may need to stop taking hormones for a few weeks before and after surgery. The surgeon will determine when this is necessary.
- If you develop enough breast tissue and are over the age of 50, your provider will recommend regular breast examinations and breast cancer screenings the same as for non-transgender women.
- Estrogen therapy for gender-affirmation is typically a lifelong treatment. Suddenly stopping estrogen treatment after you have been on it for a long time may have negative health effects.
- You may choose to stop taking estrogen therapy at any time or for any reason. Some people, based on their medical needs, may also need to decrease and/or stop estrogen therapy as they age in a way like menopause in non-transgender women. Discuss any changes to or stopping of hormone treatment with your medical provider so you can plan a safe way of slowly reducing your medication before stopping it completely.
- Your provider may decrease the dose of estrogen or androgen blockers or stop prescribing hormone therapy because of medical reasons and/or safety concerns; you can expect that the medical provider will discuss the reasons for all treatment decisions with you.

- Hormone therapy is not the only way that a person may appear more feminine and live as a female; your medical provider and/or a mental health provider can help you think about these other options.

_____ (initials) My (my child's) medical provider or member of the medical team has answered my questions feminizing hormone therapy. _____ (initials)
 Provider _____ Date discussed _____

You agree to

- Take androgen blockers and/or estrogens only at the dosage and in the form that your medical provider prescribes.
- Inform your medical provider if you are taking or start taking any other prescription drugs, dietary supplement, herbal or homeopathic drugs, or street drugs or alcohol so that you can discuss possible interactions with and effects on your hormone treatment
- Inform your medical provider of any new physical symptoms or any medical conditions that may develop before or while you are taking hormone therapy and discuss the evaluation of these conditions; inform your provider if you think you are having bad side effects from the medications.
- Keep regular follow up appointments; this may include appointments for mammograms and prostate exams
- Have regular monitoring blood testing done; your provider will discuss with you what tests are necessary in order to monitor for potential harmful effects and to ensure that your hormone therapy is safe and effective

_____ (initials) My (my child's) medical provider or member of the medical team has answered my rights and responsibilities while taking feminizing hormone therapy.
 _____ (initials) Provider _____ Date discussed _____

By signing this form, you acknowledge that you and/or your legal guardian(s) have adequate information and knowledge to be able to make an informed decision about hormone therapy and that you understand the information your medical provider has given you. Based on this information (chose one):

I _____, _____ choose to start feminizing hormone therapy
Patient's name listed on insurance or chart

—OR— _____ do not want to start hormone therapy for feminizing my body.

 Patient signature (name in chart) Date

 Patient's Date of Birth

 Patient's name used, if different from chart

 Parent/Guardian signature (1) Date

 Parent/Guardian Signature (2) Date

 Parent/Guardian signature (1) PRINTED

 Parent/Guardian Signature (2) PRINTED

 Provider signature Date

 Provider name PRINTED

If I choose (choose for my child) to start estrogen therapy, I agree to have (to bring my child for) regular physical examinations and blood tests to make sure that I am (my

child is) not having a bad reaction to estrogen. I understand that this is required to continue estrogen therapy at this clinic.

_____ (initials) Patient/guardian _____ Provider _____ Date

Informed Consent/Assent for Puberty Suppression

For _____ Date of Birth: _____ Name Used: _____
Patient Name as listed in chart Name if different from chart

There are advantages, disadvantages, and possible risks with treatment to block or suspend puberty. Please read the possible risks and effects listed below. It's important that you understand all this information before you consent to your child starting medication to suspend or put their puberty "on hold."

Read the below information carefully. Ask your child's medical providers any questions you have about treatment. When you are comfortable and understand how puberty blockers may help your child, you may sign the consent to start treatment.

The main way that the physical changes of puberty can be put on hold is by blocking the signal from the brain to the organs that make the sex hormones estrogen or testosterone. Estrogen is made by the ovaries. Testosterone is made by the testicles.

The medications are commonly called puberty blockers. They may be prescribed for use daily, monthly, or once every three months. If a person has a variation of sex development (e.g., intersex), they will need to work with a specialist (endocrinologist) to further consult regarding gender affirming hormonal treatments due to their unique medical needs. Puberty blockers may be started just following the onset of noticeable physical changes of puberty. Please talk to your medical provider about how to recognize these early changes if you are unsure what to help monitor or look for in your child.

For some trans feminine children additional medicines may be used to block the effect of testosterone. The most common medication of this type is called spironolactone. Spironolactone is not an option for all trans feminine children. Talk with your child's medical provider to go over all treatment options.

Many years of experience in treating gender diverse people and accepted, published medical guidelines on hormone treatment inform the use of hormone therapy for gender confirmation/affirmation (transition) in this health center. Continuing research on hormone therapy provides us with more information on the safety and usefulness of hormone therapy to relieve gender dysphoria or incongruence when appropriate. Nonetheless, medicine does not fully understand the long-term effects of puberty blockers across the lifespan.

Read the following information and initial each section where indicated once you are sure you understand the information and your questions have been answered to your satisfaction.

Effects of Medications for Blocking Puberty

- Puberty Blockers are used to help temporarily suspend or block the physical changes of puberty
- It can take several months for the medication to be effective. No one can predict how quickly or slowly my child's body will respond.
- This treatment is based on current medical guidelines and research. These medications have been used to help treat gender diverse youth for many years. Treatment follows the recommendations of medical specialists who work with hormones and puberty (endocrinologists). Guidelines for using these medications

for gender diverse youth when the physical changes of puberty need to be delayed are published by the Endocrine Society and the American Association of Clinical Endocrinologists, however, these medications are considered “off label” for this purpose.

- The medication effect of puberty suppression is not permanent. If my child stops taking the medication, they will restart the changes of puberty where their body development/changes paused.
- While taking these medications, my child’s body will not be making the hormones of puberty, testosterone or estrogen. This will “put on hold” my child’s physical development, though it may not stop all development, such as growing taller.
- These medicines may help my child avoid the need for future gender affirming surgeries and other treatments (i.e. chest reconstruction or augmentation, facial surgeries, electrolysis) that would otherwise be needed to reverse as many of the effects of puberty as possible.
- Children assigned male at birth who identify as female or feminine may be able to take spironolactone instead of puberty blockers to stop or decrease the effects of testosterone on their body development. Review what options are possible with your child’s medical provider.
- Stress that is present due to being gender diverse, social rejection and judgments, and needing to take any medications may cause increases in my child’s level of distress, anxiety, depression, or other mental health issues.
- My child and my family may benefit from mental health supports to reduce stress and improve or maintain the ability to cope with everyday life and medical treatments. You are encouraged to talk with the medical provider about benefits from and recommendations for individual and family therapy.

_____ (initials) My child’s medical provider or member of the medical team has answered my questions about the effects medications for puberty blocking.

_____ (initials) Provider _____ Date discussed

Possible Risks of Puberty Blockers

- These medications have been administered to children for other diagnosis for many years, safely. However, the long-term side effects and safety of these medicines are not completely understood.
- My child may or may not get taller while on these medications. Puberty suppression may prevent growth spurts and increases in bone density. Adolescents continue to grow in height while on puberty suppression, but this growth is not as fast as during puberty. Research shows that delays in bone density generally reverse after puberty is resumed or cross-sex hormones are administered.
- These medicines will stop my child’s development from puberty. Other people may notice this, especially as my child becomes older and does not develop at the same rate as their peers.
- Blocking puberty development means my child will not make fertile sperm or eggs. This means that my child would have to stop puberty blockers and complete their biological puberty in order to attempt to have their own biological children later in life (i.e., become fertile). This would also mean that my child would develop all the usual secondary characteristics typical of their assigned sex at birth. This process could take several years and there would be no guarantee of fertility. There would also be the need for possible surgeries or other treatments to reverse the effects of having gone through their biological puberty (i.e., chest reconstruction, electrolysis, facial surgeries).

_____ (initials) My child’s medical provider or member of the medical team has answered my questions about the possible risks of medications for puberty blocking.

_____ (initials) Provider _____ Date discussed

You understand that

- To support my child in taking puberty blocking medication as prescribed, I agree to tell my child’s health care provider if my child has any problems or side effects or is unhappy with the medication.
- Using these medicines to block puberty is an “off-label” use. I know this means it is not approved by the Food and Drug Administration for this specific use. I know that the medication that is recommended is based on the judgment and experience of my child’s health care providers and is based on the recommendations of the Society of Pediatric Endocrinology, the Endocrine Society, and the American Association of Endocrinologists.
- My child can choose to stop taking these medications at any time. I know that if my child decides to stop the puberty suppression medications, we need to make a safe plan to stop the medications with the help of my child’s health care provider. I understand that some forms of the medication cannot be stopped, such as implanted or large injections that absorb slowly over time, but these medicines will naturally slow down and stop on their own.

You agree to

- Schedule and bring my child to required periodic check-ups to make sure that they are responding as expected to the medications.
- Tell my child’s provider about any other medications, vitamins, supplements, or other substances that my child uses.
- Tell my child’s provider and make a safe plan to stop medications if my child decides that they want to stop blocking their biological puberty.
- Discuss any questions and concerns about puberty suppression treatment; adjustment concerns related to my child’s social environment and their gender affirmation process; changes in my child’s family, school, or social systems of support either positive or negative.

The signatures below confirm that

- My child’s health care provider has talked with me about the effects and possible risks of puberty blockers for my child, including alternative treatments as appropriate or possible.
- I understand the treatment is considered off-label at this time
- I have read the information above including the known effects and possible risks. I know that there may be unknown long-term effects or possible risks.
- I have had opportunity to discuss treatment options with my child’s health care provider.
- All my questions have been answered to my satisfaction.
- I have enough information to give informed consent to or to reject puberty blocking medications for my child at this time.

By signing this form, you acknowledge that you and your child have adequate information and knowledge to be able to make an informed decision about puberty blocking treatment and that you understand the information your medical provider has given you. Based on this information (chose one):

_____ I choose for my child, _____, to begin puberty blocking

Patient’s name listed on insurance or chart

treatment. —OR— _____ I do not want my child to start puberty blocking treatment.

Patient signature (name in chart) Date

Patient's name used, if different from chart _____
Patient's Date of Birth

Parent/Guardian signature (1) Date _____
Parent/Guardian Signature (2) Date

Parent/Guardian signature (1) PRINTED _____
Parent/Guardian Signature (2) PRINTED

Provider signature Date _____

Provider name PRINTED

Appendix C: Laboratory Monitoring

LAB MONITORING FOLLOWING INITIATION OF GNRH AGONISTS (PUBERTY SUPPRESSION)

Test	Baseline	1mo	3 mos	6 mos	12 mos	Yearly	PRN
FSH	X	X	X	X	X	Continue every 6-12 months while taking medication	
LH	X	X	X	X	X	Continue every 6-12 months while taking medication	
Endogenous Sex Hormone	X	X	X	X	X	Continue every 6-12 months while taking medication	
H & P / Tanner Staging	X	X	X	X	X	Continue every 3-6 months while taking medication	
Height / Weight	X	X	X	X	X	Continue every 3-6 months while taking medication	
Blood pressure	X	X	X	X	X	Continue every 3-6 months while taking medication	
Liver function	X	X	X	X	x		X
Lipids					X		X
Vitamin D				X	x	Continue every 6-12 months while taking medication	
Bone Age							x
DEXA	Only as clinically indicated based on underlying risk						x

LAB MONITORING FOLLOWING INITIATION OF FEMINIZING GAHT

Lab Testing	Baseline	3 mos	6 mos	12 mos	Annual	PRN
Total Testosterone	X		X	X	X	
Estradiol			X	X	X	
BUN/Cr (if on spironolactone)	X	X	X	X	X	
Lipids						X
Glucose or A1c						X
Prolactin				X		X

LAB MONITORING FOLLOWING INITIATION OF MASCULINIZING GAHT

Lab Testing	Baseline	3 mos	6 mos	12 mos	Annual	PRN
Total Testosterone			X	X	X	
Hct	X		X	X	X	
Estradiol						X
Lipids						X
Glucose or A1c						X

Appendix D: Medication Recommendation Tables

PROTOCOL FOR PUBERTY SUPPRESSION

GnRH Analog	Starting Dose	Increase
Leuprolide IM 1mo	7.5mg-11.25mg for wt ≤ 25kg 11.25-22.5mg for wt >25kg	by 3.75mg q4wks as indicated by clinical response
Leuprolide IM 3mo	7.5mg-11.25mg for wt ≤ 25kg 11.25-22.5mg for wt >25kg	to 22.5mg-30mg or shorten interval between injections
Histrelin	50mg SC implant q12mo	Shorten interval as needed
Alternative Options		
Depo-Provera	150mg q3mo	
Spirolactone	25mg daily	by 25mg daily until T suppression

PROTOCOL FOR INDUCING FEMALE PUBERTY

Medication	Starting Dose	Increase	Adult/Max Dose
Transdermal Estradiol Patch <i>(*patches will vary in interval of dosing)</i>	6.25-12.5mcg*	by 25-37.5mcg every 3-6mo based on patient age, clinical response, and lab values (target goal 100-200pg/mL)	200-400mcg
Estradiol tablets	0.25mg daily	by 0.25mg daily every 3-6 months based on patient age, clinical response, and lab values. At >2mg, can divide into twice daily dosing	6-8mg daily
Estradiol Valerate IM	5mg biweekly	by 5mg biweekly based on patient age, clinical response, and lab values	20-40mg biweekly
IF NOT USING GnRH ANALOG, USE ONE OF THE FOLLOWING			
Spirolactone	50mg daily	by 50mg weekly to achieve desired testosterone suppression	200-400mg daily (divided into twice daily dosing)
Finasteride	1mg daily	by 1mg as clinically indicated	5mg daily
Dutasteride	0.5mg daily		0.5mg daily

In post-pubertal trans feminine youth the dose of 17β-estradiol may start higher and increase faster:

Start: Oral estradiol 1mg daily

Increase: 1-2mg daily every 3-6 months based on patient age, clinical response, and lab values (target 100-200ng/dL). At >2mg, divide into twice daily dosing.

Adult dose: 6mg-8mg daily

PROTOCOL FOR INDUCING MALE PUBERTY

Medication	Starting Dose	Increase	Adult/Max Dose
Testosterone Cypionate / Enanthate	12.5mg-25mg weekly (For initiation of pubertal growth: 40 to 50 mg monthly total)	12.5mg weekly every 3-6mo based on age of patient, clinical response, and serum T levels	50-100mg every week (100-200mg every 2wks)
Topicals not recommended until adult dose is achieved unless clinically indicated			
Transdermal Testosterone Gel Formulations	20-25mg daily	by 25mg daily every 3-6 months based on patient age, clinical response, and lab values	50-100mg daily
Testosterone patches	2mg patch daily	by 2mg daily every 3-6mo based on patient age, clinical response, and lab values	4-8mg daily

In post-pubertal trans masculine youth the dose of testosterone can start higher and increase faster:

Start Injectable Testosterone: 25mg-50 mg weekly

Increase: 25mg weekly every 1-3 months based on clinical response and serum T levels (target 300-1000ng/dL)

Adult dose: 50-100mg weekly

Appendix E: Nutritional Values

NUTRITIONAL INTAKE OF CALCIUM & VITAMIN D

Recommended Calcium Intake	
Age Group	Mg/day
1 to 3 years old	700
4 to 8 years old	1,000
9 to 13 years old	1,300
14 to 18 years old	1,300
19 to 30 years old	1,000

Source: Food and Nutrition Board, Institute of Medicine, National Academy of Sciences, 2010. See: <https://ods.od.nih.gov/factsheets/VitaminD-HealthProfessional/> for more information

SERUM 25-HYDROXYVITAMIN D [25(OH)D] CONCENTRATIONS & HEALTH*

nmol/L**	ng/mL*	Health status
<30	<12	Associated with vitamin D deficiency, leading to rickets in infants and children and osteomalacia in adults
30 to <50	12 to <20	Generally considered inadequate for bone and overall health in healthy individuals
≥50	≥20	Generally considered adequate for bone and overall health in healthy individuals
>125	>50	Emerging evidence links potential adverse effects to such high levels, particularly >150 nmol/L (>60 ng/mL)

Source: Institute of Medicine, Food and Nutrition Board. Dietary Reference Intakes for Calcium and Vitamin D. Washington, DC: National Academy Press, 2010.

* Serum concentrations of 25(OH)D are reported in both nanomoles per liter (nmol/L) and nanograms per milliliter (ng/mL).

** 1 nmol/L = 0.4 ng/mL

RECOMMENDED DIETARY ALLOWANCES (RDAS) FOR VITAMIN D

Age	Assigned Male	Assigned Female	Pregnancy	Lactation
1-13 years	600 IU (15 mcg)	600 IU (15 mcg)		
14-18 years	600 IU (15 mcg)	600 IU (15 mcg)	600 IU (15 mcg)	600 IU (15 mcg)
19-50 years	600 IU (15 mcg)	600 IU (15 mcg)	600 IU (15 mcg)	600 IU (15 mcg)

Source: Institute of Medicine, Food and Nutrition Board. Dietary Reference Intakes for Calcium and Vitamin D. Washington, DC: National Academy Press, 2010.

Appendix F: Bone Health and Adult Height

Baseline information about bone density may provide benefits, however there are no evidence based guidelines, nor is there consensus about the necessity of obtaining bone densitometry prior to, and during puberty suppression treatment. Baseline screening is recommended when there is a family history of non-traumatic bone fractures or osteoporosis. To optimize bone health, providers should confirm adequate dietary intake of calcium and should monitor vitamin D levels (25-OH) and supplement if indicated. Weight-bearing activity should also be encouraged. Physical changes of puberty should be assessed at follow up visits. [1]

Gender diverse youth continue to grow in height while undergoing puberty suppression, however bones will continue to grow at pre-pubertal rates. Research indicates that youth who start medically managed gender affirming hormone therapy following puberty suppression may reach a final adult height more closely in the range associated with their affirmed gender rather than their sex assigned at birth [2, 3]. Research also shows that any delays in bone density formation generally catch-up to age-matched peers after puberty is resumed or gender affirming hormones are administered. In addition, studies consistently find that GnRH analogs do not affect body proportions or body mass index (e.g., weight in relation to height) over time [4, 5, 6]. Even so, endocrinology treatment guidelines recommend regular testing of height and weight (every 3 months), and to consider bone density screening and bone age if indicated (every 6-12 months) [7, 8].

Because endogenous sex hormones are involved in initial growth and then closure of the epiphyseal growth plates, and therefore terminal height, it is necessary to consider the impact and timing of initiating and increasing these exogenous hormones for gender affirming care. [14] In humans, it appears that estrogen is responsible for both the initial pubertal growth spurt and closure of the growth plates in all sexes, while testosterone plays a smaller. [15] When appropriate, an earlier initiation of estrogen in a trans feminine youth may promote earlier closure of their growth plates, therefore limiting height to align more closely with a feminine affirmed gender. Alternatively, trans masculine youth may benefit from a delay in initiating testosterone and then starting a low doses with slow ramp up, in order to decrease aromatization to estrogen and early closure of growth plates. This may allow increased height to match more closely that of the masculine affirmed gender.

Final adult height is strongly determined by genetic factors, however it also varies by where a person was born and raised, by birth weight, prematurity, disease, nutrition, environmental exposures, and overall health. If a youth is growing at an unusual rate or does not seem to be growing as expected, a referral to endocrinology for an assessment is recommendation.

For youth entering gender affirming care, the clinician should record a current height and a calculated final adult height in the patient chart. Current height should be plotted on the stature chart appropriate to the patient's gender identity. It is especially important to attend to height changes around age 13 when growth and final adult height begins to diverge significantly between patients assigned male and assigned female sex at birth.

Concerns that warrant further exploration for treatment include atypically short or tall predicted final adult height in relation to the gender of identity of the youth. In the United States, short stature is generally considered a person who has a final adult height below the 3rd percentile for their age and sex and other factors affecting height for that individual. Tall stature is generally considered a person who has a final adult height above the 95th percentile. [16]

For Trans Masculine Youth:

The concern for trans masculine youth may be a predicted final adult height below the 3rd percentile for adult men. Typically, patients assigned female sex at birth reach final adult height 18 months after menarche, and this information will help determine what treatment options are still possible and the timeliness of puberty suppression or GAHT initiation. If the youth's current height falls at or below the 5th percentile for age on the boys' stature chart, or if the calculated final adult height falls at or below the 5th percentile at age 20 on the same chart, a bone age is recommended. If the bone age assessment indicates opportunity for ongoing skeletal growth, the patient should be referred to pediatric endocrinology for an assessment and recommendations for treatment to maximize potential adult height.

For Trans Feminine Youth:

The concern for trans feminine youth is a predicted final adult height above the 95th percentile for adult women. If the youth's current height is greater than the calculated final adult height estimate formula at the initial visit or at any subsequent visit; the patient's height crosses more than one percentile curve of the girls' stature chart over subsequent appointments; or the patient's height approaches the 95th percentile on the girls' stature chart in

any visit, refer for an endocrine assessment and recommendations. If bone age assessment shows considerable likelihood for growth, it may be appropriate to start low dose estrogen in order to close growth plates and prevent a final adult height that may exacerbate dysphoric symptoms, as described above.

Vitamin D Screening

Correct levels of Vitamin D, along with other factors, contribute to bone health and modify risks for future osteoporosis. Screening is recommended for children at baseline and annually prior to initiating treatment with Leuprolide Acetate or other puberty suppressing medications, which may lead to bone loss when used long term. Vitamin D repletion and maintenance should be started for anyone with lower than recommended Vitamin D levels. Other factors that affect bone health include adequate dietary intake of calcium, weight-bearing activity, and alcohol consumption less than 2-3oz daily. (see: <https://www.bones.nih.gov/health-info/bone/osteoporosis/overview#c>)

DEXA Scanning

The most common bone mineral density (BMD) test is a central dual-energy x-ray absorptiometry, or central DEXA test. DEXA scans, when indicated for youth with high-risk of bone fracture or other bone health issues, [7, 8] are typically ordered and reviewed by an appropriate specialist. Youth with these concerns who are considering puberty suppression need close collaboration between all specialists and/or primary care providers, and the clinician managing puberty suppression. In those situations where a Fenway Health clinician is the first provider to identify a high-risk youth, it is strongly recommended that the youth be referred to a specialist for evaluation of bone health before starting any puberty suppressing medications.

Adult Height Worksheet

Trans-masculine youth under age 20 and on hormone therapy.

Use Growth Charts on following pages to find percentiles.

Date of birth: ___/___/_____

Growth chart age: _____

Calculated Final Adult Height - Male Calculated Final Adult Height - Female

Mother's Height: _____
(in inches)

Father's Height: _____
(in inches)

+ 5

-5

Total: _____

÷ 2

÷ 2

Final Adult Height Estimate B _____
(copy to B below)

A _____
(copy to A below §)

Male Percentile Height

Female Percentile

Current _____

Final adult Height A _____
Female Curve (§ use larger of A or current height)

_____*

Final adult Height B _____
Male Curve

_____*

Difference _____*

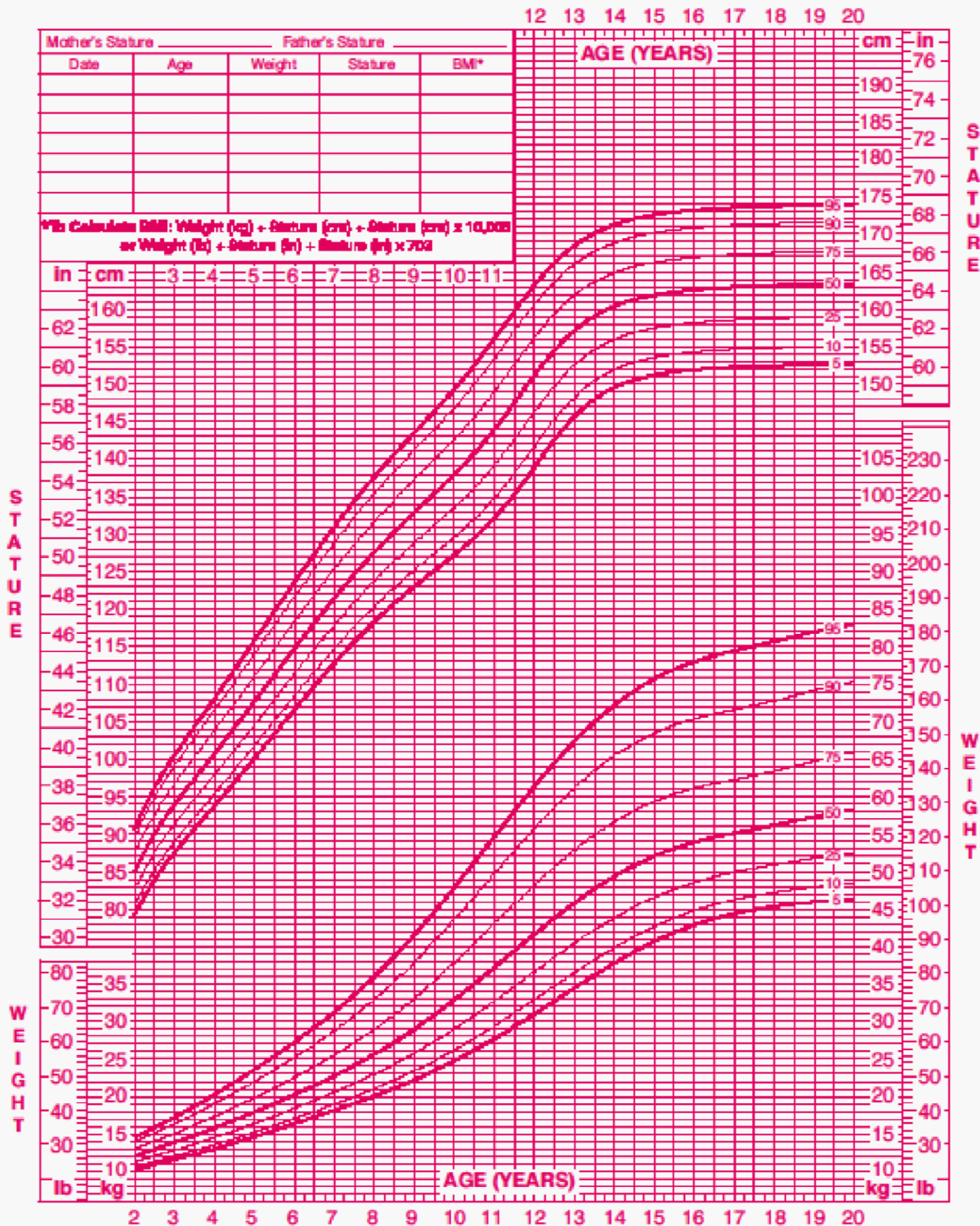
**If final adult height using the female or the male growth chart is equivalent to or less than the 5th percentile on the male stature chart or Difference is greater than 2.5, consider a bone age to assess for potential future growth or refer to endocrinology for assessment and recommendations.*

2 to 20 years: Girls

Stature-for-age and Weight-for-age percentiles

NAME _____

RECORD # _____



Published May 30, 2000 (modified 11/21/00).

SOURCE: Developed by the National Center for Health Statistics in collaboration with the National Center for Chronic Disease Prevention and Health Promotion (2000).
<http://www.cdc.gov/growthcharts>



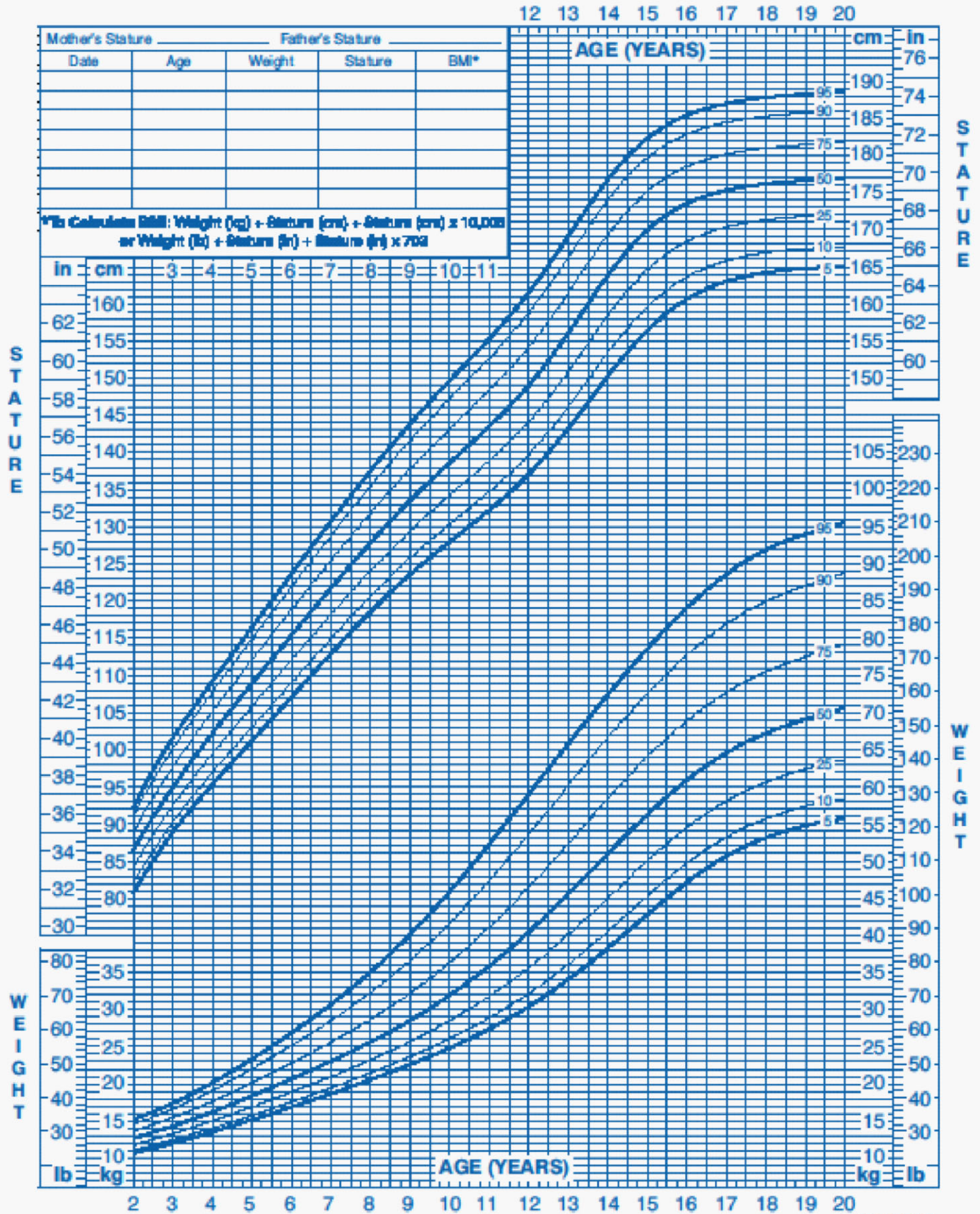
SAFER • HEALTHIER • PEOPLE

2 to 20 years: Boys

Stature-for-age and Weight-for-age percentiles

NAME _____

RECORD # _____



Published May 30, 2000 (modified 11/21/00).

SOURCE: Developed by the National Center for Health Statistics in collaboration with the National Center for Chronic Disease Prevention and Health Promotion (2000).
<http://www.cdc.gov/growthcharts>



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