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guidelines for gender-affirming primary care with trans and non-binary patients

A QUICK REFERENCE GUIDE FOR PRIMARY CARE PROVIDERS (PCPs)

This quick reference guide was derived from Sherbourne's *Guidelines for Gender-Affirming Primary Care with Trans and Non-Binary Patients* and is designed to be used in conjunction with the full Guidelines.

Key messages

- Prescribing hormone therapy for trans patients is well-situated in primary care.
- The risks of witholding hormone therapy are often more substantial than the risks of treatment.

AN INDIVIDUALIZED APPROACH

Given the spectrum of gender identity and the variation in each person's expression, there is no single pathway for a trans person to follow in order to actualize the presentation of their authentic self. Non-binary patients may also seek hormone therapy to modify their secondary sex characteristics.
When hormones are chosen as part of transition, some patients may seek maximum feminization/ masculinization, while others may seek a more androgynous appearance.

DECISION TO INITIATE HORMONE THERAPY

The decision to initiate hormone therapy is a collaborative patient-centered process that focuses on both psychosocial preparation and informed consent. The PCP (with or without the support of a multi-disciplinary team) can facilitate a decision-making process that informs, educates and supports patients. For each patient seeking hormone therapy, it is important to not only consider the possible risks of treatment but to consider the often substantial risks of witholding treatment.

TERMINOLOGY

CIS: Refers to a state of alignment of one's gender identity with the gender assigned at birth. You may also sometimes see "cissexual" or "cisgender." Thus, non-trans men are "cis men" and non-trans women are "cis women." It is preferable (and more accurate) to use "cis" than to use terms such as "bio", "genetic" or "real." It is also preferable to use "cis" rather than only using "woman" or "man" to describe non-trans persons. If cis is not used as a descriptor for non-trans persons, then such persons may be presumed to be the more "normal" or "valid" instantiation of that particular gender, thus contributing to cissexism.

TRANS: Umbrella term for people who are not cis, includes persons who are (or identify as) non-binary as well as transmasculine and transfeminine individuals.

NON-BINARY: Umbrella term for anyone who does not identify with static, binary gender identities. Includes persons who may identify as having an intermediary gender (e.g. genderqueer), as being multiple genders (e.g. bigender, polygender, etc.), as having a shifting gender (gender fluid), or as not having a gender altogether (agender).

DISCLAIMER:

These guidelines reflect the current practice at Sherbourne Health in the management of trans patients. We do not present it as a 'Standard of Care' but instead as a guide to help clinicians in their day-to-day practice. Adaptions may be considered relating to each patient's unique circumstances. Clinicians must use their own expertise and decision-making skills within each clinical encounter.

Masculinizing hormone therapy

The cornerstone of hormone therapy for transmasculine patients is testosterone. The goal of treatment is virilization – the development of masculine secondary sex characteristics. This treatment results in both reversible and irreversible masculinization.

TESTOSTERONE

In Ontario, options for testosterone administration include injectable and transdermal preparations (patch or gel). Injectable formulations are most commonly used, due to their superior efficacy and affordability. While intramuscular (IM) injection is the most common means of administering parenteral testosterone, subcutaneous (SC) delivery has also been used with clinical efficacy and is very well-tolerated. A dose reduction of 10-15% can be considered if switching from IM to SC.

PRECAUTIONS

Evidence compiled by the Endocrine Society suggests that masculinizing hormone therapy is "**safe without a large risk of adverse events when followed carefully for a few well-documented medical concerns**".[1] Available measures to reduce associated risks should be considered and discussed with patients and if possible, undertaken prior to or concurrently with the initiation of hormone therapy. Suggested measures to minimize risk associated with known precautions may be found in the full Guidelines.

Contraindications

- Pregnancy or breast feeding
- Active known sex-hormone-sensitive cancer (e.g., breast, endometrial)
- Unstable ischemic cardiovascular disease
- Poorly controlled psychosis or acute homicidality
- Psychiatric conditions which limit the ability to provide informed consent
- Hypersensitivity to one of the components of the formulation

SAFETY

Gel formulations have the risk of inadvertent exposures to others who come into contact with the patient's skin. This is of particular importance for patients with young children and/or with intimate partners who are pregnant or considering pregnancy.

Keep in mind:
Testosterone therapy does not prevent pregnancy even if amenorrhea is achieved. Testosterone is a teratogen thus reliable contraception may be required depending on sexual practices.

PREVENTIVE CARE

Transmasculine patients maintained on masculinizing hormone therapy have unique preventive care needs and recommendations. An adapted *Preventive Care Checklist* for transmasculine patients that can be used at the point of care can be found in the full Guidelines.

FORMULATIONS AND RECOMMENDED DOSES OF TESTOSTERONE

Formulations	Starting Dose	Maximum Dose	Cost per unit*	Approx. Cost* (4 weeks)
Testosterone enanthate (IM/SC)[a]	20–50 mg q weekly or 40–100 mg q 2 weeks	100 mg q weekly or 200 mg q 2 weeks	$73.50 per 5mL vial (each vial contains 200 mg/mL x 5 mL = 1000 mg)	$14–$29 (covered by ODB with EAP request)
Testosterone cypionate (IM/SC)[a]			$64 per 10 mL vial (each vial contains 100 mg/mL x 10 mL = 1000 mg)	$13–$26 (covered by ODB with EAP request)
Testosterone path (transdermal)[b]	2.5–5 mg daily	5–10 mg daily	$164 / 60 x 2.5 mg patches $169 / 30 x 5 mg patches	$76.50–$315
Testosterone Gel 1% (transdermal)	2.5–5 g daily (2–4 pumps, equivalent to 25–50 mg testosterone)	5–10 g daily (4–8 pumps, equivalent to 50–100 mg testosterone)	$67 / 30 x 2.5 g sachets $110 / 30 x 5g sachets $175 / 2 pump bottles[c]	Sachets: $62–$205 Bottles: $81–$327

** Price quotes provided by www.pharmacy.ca. The prices listed above are accurate as of June 2018 and represent the price of the generic brand of medication unless otherwise indicated (ranging from low dose to maximum dose). Prices include a usual and customary dispensing fee of $9 99, which may vary from pharmacy to pharmacy.*
a) Testosterone enanthate is compounded in sesame oil, and testosterone cypionate is compounded in cottonseed oil; patients with allergy to either of these compounds should use the alternative agent
b) Androderm brand, per drug monograph the 12.2 mg patch delivers 2.5 mg/day while the 24.3 mg patch delivers 5 mg per day
c) Each pump bottle provides 60 pumps, 1 pump = 1.25 g of gel, equivalent to 12.5 mg of testosterone

NB: Testosterone (in all forms) is considered a controlled substance in Canada; prescriptions should be written in accordance with provincial requirements for controlled substances.

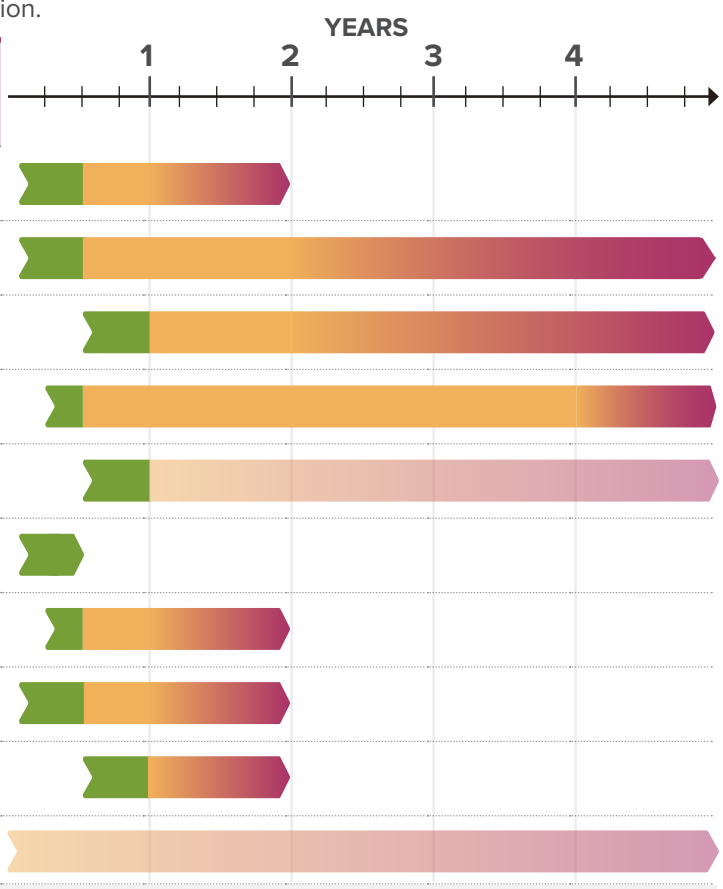
REFERENCES

1. *Weinand J, Safer J. Hormone therapy in transgender adults is safe with provider supervision; A review of hormone therapy sequelae for transgender individuals. J Clin Transl Endocrinol. 2015;2(2):55–60.*

EFFECTS AND EXPECTED TIME COURSE OF TESTOSTERONE

The degree and rate of physical effects is dependent on the dose and route of administration,[2] as well as patient-specific factors such as age, genetics, body habitus and lifestyle. Hormone therapy results in both reversible and irreversible masculinization.

Physical Effects	Reversibility	Onset[a]	Expected maximal effect[a]
Skin oiliness/acne	Reversible	1-6 months	1-2 years
Body fat redistribution	Reversible/ Variable	1-6 months	2-5 years
Increased muscle mass/strength[b]	Reversible	6-12 months	2-5 years
Facial/body hair growth	Irreversible	3-6 months	4-5 years
Scalp hair loss	Irreversible	6-12 months[c]	Variable
Cessation of menses	Reversible	1-6 months	n/a
Clitoral enlargement	Irreversible	3-6 months	1-2 years
Vaginal Atrophy	Reversible	1-6 months	1-2 years
Deepened voice	Irreversible	6-12 months	1-2 years
Infertility	Variable	Variable	Variable

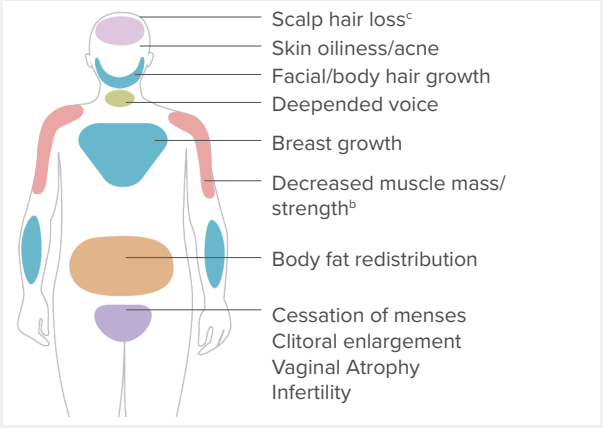


Keep in mind:

Use patient-preferred terminology. Terminology such as “clitoral” and “vaginal” may be upsetting to some but not all.

Desired androgenic effects of testosterone therapy include deepened voice, cessation of menses, clitoral growth, increased muscle mass, and hair growth in androgen dependent areas including facial hair. Breast tissue may lose glandularity, but generally does not lose mass or hemi circumference. Typically, patients taking testosterone will experience masculinizing changes over a period of months to years. The timeframe of physiologic changes may be slightly slower with the use of transdermal preparations.

a) Estimates represent published and unpublished clinical observations[3-6]
b) Significantly dependent on amount of exercise
c) Highly dependent on age and inheritance; may be minimal



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3. *Toorians AWFT, Thomassen MCLGD, Zweegman S, Magdeleyns EJP, Tans G, Gooren LJG, et al. Venous thrombosis and change of hemostatic variables during cross-sex hormone treatment in transsexual people. The Journal of Clinical Endocrinology & Metabolism 2003;88(12):5723-5729.*
4. *Asscheman H, Gooren LJG, Assies J, Smits JPH, Slegte R. Prolactin levels and pituitary enlargement in hormone-treated male-to-female transsexuals. Clin Endocrinol (Oxf)1988; 28(6): 583-588.*
5. *Gooren LJ, Harmsen-Louman W, van Kessel H. Follow-up of prolactin levels in long-term oestrogen-related male-to-female transsexuals with regard to prolactinoma induction. Clin Endocrinol (Oxf) 1985; 22(2): 201-207.*
6. *Wierckx K, Gooren L, T’Sjoen G. Clinical Review: Breast Development in trans feminine patients Receiving Cross-Sex Hormones. The Journal of Sexual Medicine 2014;11(5):1240-1247.*
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MONITORING STRATEGIES & DOSE ADJUSTMENTS

- Standard monitoring of testosterone should be employed at baseline, 3, 6, and 12 months; and yearly thereafter.
- Some clinicians prefer to see patients monthly until an effective dose is established.
- Follow up visits should include a functional inquiry, targeted physical exam, blood work, and health promotion/disease prevention counselling as indicated.
- Titration of doses will generally occur in the early phases of treatment. For example, with injectable testosterone, a starting dose of 30 mg injected weekly could be increased by 10–20 mg every 4–6 weeks. Speed of titration will depend on lab results, patient goals, response, and side effects.
- For those using an injectable route, there may be utility in varying the timing of blood work to gather information regarding serum hormone levels throughout the cycle (peak, mid-cycle, and trough), especially if a patient is reporting cyclic symptoms.
- Hormone levels for those seeking a more androgynous appearance may intentionally be mid-range between male and female norms.
- Supraphysiologic levels should be avoided due to the increased risk of adverse events and side effects, as well the potential for the aromatization of excess testosterone into estrogen. Dose reduction is warranted if supraphysiologic doses are measured at mid-cycle or trough.
- There may be some irregular bleeding or spotting in the first few months of treatment. However, once sustained menstrual cessation is achieved, any vaginal bleeding without explanation (e.g. missed dose(s) or lowered dose of testosterone) warrants a full workup for endometrial hyperplasia/cancer.

Keep in mind:
Clinical effects are the goal of therapy, not specific lab values. If the sex marker associated with the patient's health card has not been changed, the reported reference ranges will refer to the sex assigned at birth. Reference ranges vary between laboratories - refer to reference ranges from the specific laboratory (often available online or by request from the lab).

HORMONE MONITORING SUMMARY FOR TRANSMASCULINE PATIENTS

In this table, smaller and lighter grey checkmarks indicate parameters that are measured under particular circumstances.

Non-hormone labs:
Male reference ranges should be used for Hb/Hct (lower limit of female range can be used if menstruating).

	Baseline	Month 3	Month 6	Month 12[b,c]	Yearly	According to guidelines for cis patients, or provider discretion
Exam/ Investigations	Focused Physical Exam with PAP if indicated. Include: height, weight, BP.	BP, weight			See ***Preventive Care Checklist for Transmasculine Patients*** and accompanying explanations in the ***Guidelines for Gender-Affirming Primary Care with Trans and Non-Binary Patients.***	
BLOODWORK						
CBC	✓	✓	✓	✓	✓	
ALT	✓		✓[c]			✓
HbA1c or Fasting Glucose	✓		✓[c]			✓
Lipid profile	✓		✓[c]			✓
Total Testosterone	✓	✓	✓	✓	✓	
LH[a]	✓			✓	✓	

NB: Individual parameters should be considered more frequently if concerns identified or existing factors are present
a) Post-gonadectomy: Elevated LH may have implications regarding bone mineral density (See full Guidelines)
b) During first year of treatment only
c) Once at either 6- or 12-month mark

This Quick Reference Guide for pimary care providers was authored by Dr. Amy Bourns and produced by Rainbow Health Ontario, a program of Sherbourne Health, to accompany the ***Guidelines for Gender-Affirming Primary Care with Trans and Non-Binary Patients, 4th edition.***

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