MASCULINIZING HORMONE THERAPY

The cornerstone of hormone therapy for trans men is testosterone. The goal of treatment is virilization – development of masculine secondary sexual characteristics. This treatment results in both reversible and irreversible masculinization.

ABSOLUTE CONTRAINDICATIONS

- Pregnancy or breast feeding
- Active known androgen-sensitive cancer
- Unstable ischemic cardiovascular disease
- Active endometrial cancer
- 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

TESTOSTERONE

In Ontario, options for testosterone administration include injectable and transdermal preparations (patch or gel). Injectable formulations are most commonly used, both because of their superior efficacy and lower price.
Nurse practitioners (NPs) in Ontario are unable to prescribe testosterone due to its classification as a controlled substance; NPs providing trans care may opt to work collaboratively with a physician to overcome this restriction.

PRECAUTIONS

All reasonable measures should be taken to reduce the risks associated with testosterone therapy. Suggested measures to minimize risks associated with listed precautions may be found in the Guidelines and Protocols for Hormone Replacement Therapy and Primary Health Care for Trans Clients.

PREVENTIVE CARE

Trans men maintained on masculinizing hormone therapy have unique preventive care needs and recommendations.
An Adapted Preventive Care Checklist for trans men that can be used at the point of care can be found in the full protocols.

RELATIVE SAFETY

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

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.

Formulations and recommended doses of testosterone

Formulations	Starting Dose	Maximum Dose	Cost Per Unit	Approx. Cost* (4 weeks)
Testosterone enanthate (IM)	50mg q week or 100 mg q 2 weeks	100mg q week or 100 mg q 2 weeks	$69.03 per vial (each vial contains 200mg/mL x 5mL = 1000mg)	$13.81 - $27.60 **Generally approved by ODB with EAP request**
Testosterone cyponiate (IM)	50mg q week or 100 mg q 2 weeks	100mg q week or 100 mg q 2 weeks	$43.31 per vial (each vial contains 100mg/mL x 10mL = 1000mg)	$8.66- $17.32 **Generally approved by ODB with EAP request**
Testosterone Patch (transdermal)	2.5 - 5 mg OD	5 - 10 mg OD	$159.27 / 60 x 2.5mg patches $159.27 / 30 x 5mg patches	$74.33 - $297.30
Testosterone Gel (transdermal)[i]	2.5 - 5g OD (2-4 pumps, equivalent to 25-50 mg testosterone)	5 - 10g OD (4-8 pumps, equivalent to 50-100 mg testosterone)	$85.90 / 30 x 2.5g patches $147.29 / 30 x 5g patches $167.55 / 2 pump bottles[j] **Only gel in packets (not in pump form) covered by ODB**	Sachets $80.17 - $274.94 Bottles $78.19 - 312.76
Testosterone Gel (transdermal, axillary)[k]	1.5 - 3g OD (1-2 pumps, equivalent to 30-60 mg testosterone)	3 - 4.5mL OD (2-3 pumps, equivalent to 60-90 mg testosterone)	$166.89 / pump bottle[l] **Only gel in packets (not in pump form) covered by ODB**	$77.88[a] - $233.65 **Axiron not covered by ODB**

*Price quotes provided by www.pharmacy.ca. The above-mentioned prices are accurate as of February 4th, 2015 and represent the price of the generic brand of medication where available (unless otherwise indicated). Prices include a usual and customary dispensing fee of $9.99, which may vary from pharmacy to pharmacy.

i) Androgel® 1% gel
j) each pump bottle provides 60 doses of 1.25g (=12.5mg testosterone)
k) Axiron™ 2% solution
l) each pump bottle provides 60 doses of 1.5 mL (=30mg testosterone)

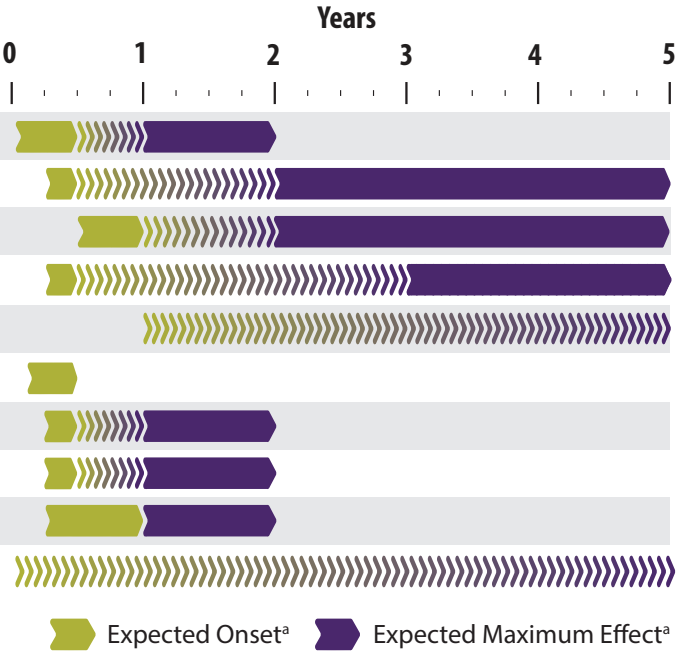
For more information, please visit the Trans Primary Care website at www.rainbowhealthontario.ca

EFFECTS AND EXPECTED TIME COURSE OF A REGIMEN CONSISTING OF TESTOSTERONE

The degree and rate of physical effects is dependent on the dose and route of administration, as well as client-specific factors such as age, genetics, body habitus and lifestyle.

Hormone treatment results in both reversible and irreversible masculinization.

PHYSICAL EFFECT	REVERSIBILITY	ONSET
Skin oiliness/acne	Reversible	1 - 6 months
Body fat redistribution	Reversible/Variable	3 - 6 months
Increased muscle mass/strength[b]	Reversible	6 -12 months
Facial/body hair growth	Irreversible	3 - 6 months
Scalp hair loss	Irreversible	variable
Cessation of menses	Reversible	2 - 6 months
Clitoral enlargement	Irreversible	3 - 6 months
Vaginal atrophy	Reversible	3 - 6 months
Deepened voice	Irreversible	3 - 12 months
Infertility	Irreversible	variable



a) Estimates represent published and unpublished clinical observations
b) Significantly dependent on amount of exercise

MONITORING STRATEGIES & DOSE ADJUSTMENTS

As with treatment for trans women, monitoring should be done at 1, 3, 6 and 12 months after starting therapy. This should include a functional inquiry, targeted physical exam, bloodwork, and health promotion/disease prevention counselling as indicated. Titration of doses will occur in the early phases of treatment (i.e. after bloodwork done at 1 or 3 months).

There may be utility varying the timing of bloodwork (ie. trough vs. midcycle) to gather information regarding serum levels throughout the injection cycle. For clients seeking maximum masculinization, the target dose will bring the free and total testosterone levels into the physiologic male range. Dose reduction is warranted if supraphysiologic doses are measured at mid-cycle or trough.

Once 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 and cancer including endometrial biopsy.

Clinical effects are the goal of therapy, not specific lab values

HORMONE MONITORING SUMMARY FOR TRANS MEN

	BASELINE	MONTH 1	MONTH 3	MONTH 6
EXAM/ INVESTIGATION	Full Physical Exam with PAP if indicated, include height, weight, waist & abdo circ. EKG if over 40, EKG + cardiac stress test if additional risk factors	BP, weight, waist & abdo circ., abdominal exam including liver palpation		BP, weight, waist and abdo circ., abdominal exam including liver palpation
BLOODWORK				
CBC	✓	✓	✓	✓
ALT/AST[a]	✓	✓	✓	✓
Fasting Glucose	✓			✓
LDL/HDL/TG	✓			✓
Testosterone (+/- Estradiol)	✓	✓	✓	✓
LH[b]	✓			
Other	Hep A, B, C Pregancy test (before first injection)			

a) for Ontario providers who may be restricted in ordering OHIP- covered AST levels, ALT alone may be used to screen for liver dysfunction
b) Elevated LH post-gonadectomy may have implications regarding bone mineral density (See Osteoporosis and BMD Screening)