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MEMORANDUM FOR DIRECTORS, DEFENSE HEALTH NETWORKS
DIRECTORS, MILITARY MEDICAL TREATMENT FACILITIES

SUBJECT: Clinical Practice Guideline for Testosterone Deficiency in the Male Service Member

The updated clinical practice guideline for Testosterone Deficiency in the Male Service Member (Attachment) is available at www.dha.mil/HHPO. Clinical and Periodic Health Assessment questions will be updated to match this policy. The female clinical practice guideline is being reviewed and will be posted upon approval.

Clinical educational materials are being updated and will be posted on Joint Knowledge Online.

DARIN VIA
Vice Admiral, Medical Corps, United States Navy
Director, Defense Health Agency

Attachment:
Clinical Practice Guideline for Testosterone Deficiency in the Male Service Member

cc:
Assistant Secretary of War for Health Affairs
Joint Staff Surgeon
Surgeon General, Department of the Army
Surgeon General, Department of the Navy
Surgeon General, Department of the Air Force
Defense Health Agency, Assistant Directors
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CLINICAL PRACTICE GUIDELINE

Testosterone Deficiency in the Male Service Member

This CPG provides indications for, and the procedures associated with, the screening, diagnosis, and management of testosterone deficiency in male Service members.

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TESTOSTERONE DEFICIENCY — CLINICAL QUICK REFERENCE

WHO IS SCREENED

- All male SMs age 30+ at the PHA (structured symptom and risk assessment)
- SMs under 30 upon request

HOW IT IS CONFIRMED

- Two morning fasting total testosterone levels (0700–1000) on separate days
- One LH/FSH set with the repeat draw
- Assess free T when total T is in range and symptoms persist

WHEN NOT TO TEST

- Within 30 days of training involving extreme physical or mental distress and/or sleep deprivation
- During acute illness, or within 30 days of recovery of that illness

DIAGNOSIS	▪ Total T < 300 ng/dL on two morning fasting specimens PLUS consistent symptoms ▪ Total T in range but low free T (<66pg/ml) PLUS consistent symptoms (LH and FSH once, with the repeat draw, to determine the level of the defect) (Figures 1 and 2)
BEFORE TREATING	▪ Hematocrit is mandatory before treating ▪ If over 40, PSA before treating — above 3 ng/mL, refer to Urology ▪ Baseline labs: total T ×2 (free T if indicated), LH/FSH, Hgb/Hct, PSA if over 40 ▪ Offer lifestyle intervention for reversible causes (i.e obesity) — but do not withhold treatment during this time ▪ Ask about fertility intent before any prescription (Figure 3)
IF FERTILITY DESIRED	▪ Do NOT start exogenous testosterone ▪ hCG (on label) or clomiphene (off label) — see Appendix E ▪ Offer optional baseline semen analysis and discuss sperm cryopreservation (when appropriate) before starting any therapy
DOSING	▪ Select by compliance, ability to achieve appropriate blood concentrations, and convenience ▪ Injections (SQ or IM): cypionate or enanthate 100 mg weekly, or 50 mg twice weekly ▪ Oral undecanoate: 200–237 mg BID with a fatty meal (> 15 g). Gel 1.62%: 40.5 mg once daily
TARGET	▪ Titrate on trough, drawn before the next dose or the day it is due ▪ Trough < 300 ng/dL → increase. 300–600 ng/dL → maintain. ≥ 600 ng/dL → decrease ▪ Symptomatic within target → evaluate free T and SHBG (Figure 4)
MONITORING	▪ Trough T and hematocrit at 4–6 weeks after initiation or any dose change, then every 6 months ▪ Labs at minimum: testosterone and hematocrit every 6 months; PSA annually if over 40 ▪ Target trough achieved with no meaningful symptom improvement by 6 months → reconsider the diagnosis
ERYTHROCYTOSIS	▪ Baseline HCT > 50%: do not start until the etiology is explained (i.e. OSA, polycythemia vera, tobacco) ▪ On therapy > 52%: recommend blood donation or therapeutic phlebotomy, reducing the dose, or withholding ▪ On therapy ≥ 54%: stop until below 50%; suggest donation or phlebotomy (Figure 5)
DEPLOYMENT	▪ May initiate testosterone within 90 days of deployment and may be deployed if testosterone levels are stable and no longer require titration prior to deployment ▪ Stable on therapy does not require a waiver for deployment ▪ Confirm supply for the deployment plus 90 days — see Appendix C

PERFORMANCE METRICS

- Documented symptom and risk assessment at the PHA
- Specimens drawn under valid pre-test conditions
- Diagnosis supported by two morning fasting specimens
- Hematocrit obtained before treating
- Fertility intent documented before prescription
- Trough level and hematocrit at 4–6 weeks and every 6 months

EXECUTIVE SUMMARY

Testosterone deficiency is a clinical syndrome requiring both a consistently low morning serum testosterone concentration and a compatible symptom profile.[1,2] Neither element establishes the diagnosis alone. Symptoms attributable to androgen deficiency — reduced libido, loss of spontaneous morning erections, erectile dysfunction, diminished energy and physical performance, impaired concentration, reduced muscle mass, and depressed mood — overlap substantially with the effects of sleep restriction, caloric deficit, psychological stress, mild traumatic brain injury, and mood disorders, all of which are prevalent in the operational population.[1,2,24]

Prevalence depends heavily on definition. Isolated biochemically low total testosterone is common and rises with age and adiposity. When both biochemical and symptomatic criteria are applied, prevalence is substantially lower: the European Male Ageing Study reported 2.1 percent across ages 40 to 79, and 0.1 percent at ages 40 to 49.[18] Defense Medical Surveillance System records for 2018 through 2025 indicate that fewer than 1 percent of male Service members carried an active clinical diagnosis annually.

Testosterone therapy has demonstrated benefit for sexual function and improves body composition and bone mineral density.[7,9,10] Evidence does not support its use to improve energy, vitality, physical function, or cognition, and the American College of Physicians recommends against initiating therapy for those indications.[5] In the Testosterone Trials, the prespecified primary endpoints for vitality and for walking distance were both null.[10] Guidance premised on performance enhancement rather than on treatment of a diagnosed deficiency is not supportable on the current evidence.

The central diagnostic challenge in this population is not detection. It is discrimination. Intense physical training, sleep restriction, caloric deficit, and sustained operations produce transient suppression of the hypothalamic-pituitary-gonadal axis that typically resolves within days of adequate recovery.[24] This adaptive suppression is not hypogonadism, and treating it as such exposes Service Members to unnecessary therapy, suppresses endogenous production, and compromises fertility. This CPG accordingly specifies pre-test conditions with the same rigor it applies to treatment.

This CPG applies to male Service members. Female Service members are addressed in a companion CPG.

BACKGROUND

Classification, and Why It Governs Management

Primary hypogonadism reflects testicular failure: low testosterone with elevated LH and FSH. Secondary hypogonadism reflects hypothalamic or pituitary dysfunction: low testosterone with low or inappropriately normal gonadotropins. Functional hypogonadism is a subset of the secondary form in which gonadotropin secretion is suppressed by an identifiable and often reversible condition — adiposity, opioid or glucocorticoid exposure, systemic illness, obstructive sleep apnea, excess alcohol, or energy deficit — without structural pathology.[1,6]

The Operational Overlay

Sleep restriction, negative energy balance, high training volume, thermal and altitude stress, and psychological load each suppress the axis, and their effects are additive.[24] Suppression under these conditions is an adaptation to energy scarcity, not a disease, and it typically resolves within days of restored sleep and intake. A specimen drawn during or immediately after such a period does not reflect baseline, and a diagnosis founded on one will be wrong in a substantial proportion of cases. This is the central diagnostic problem in this population, and the pre-test conditions below exist to control for it.

SCREENING

Population and Frequency

All male Service members aged 30 years and older will undergo screening for testosterone deficiency as a component of the Periodic Health Assessment, upon entry to the military, or at annual physical examination. Screening consists of a structured symptom and risk-factor assessment. Male Service members under age 30 will be screened on request, or where clinical indicators are identified by the examining provider.

Screening Instrument

The provider will document the presence or absence of each of the following symptoms, together with the risk factors listed below:

- Reduced sexual desire
- Loss of spontaneous morning erections
- Erectile dysfunction
- Diminished physical performance or endurance not explained by training status or injury
- Impaired concentration or memory
- Unexplained loss of muscle mass or gain in fat mass
- Depressed mood, low motivation, or disturbed sleep

Risk factors: obesity; type 2 diabetes or metabolic syndrome; chronic opioid or glucocorticoid therapy; prior traumatic brain injury with loss of consciousness; testicular trauma, torsion, undescended testis, orchitis, or prior chemotherapy or pelvic radiation; known or suspected obstructive sleep apnea; low-trauma fracture; recurrent bone stress injury; unexplained anemia; infertility; gynecomastia.

Interpretation

The combination of reduced sexual desire, loss of spontaneous morning erections, and erectile dysfunction have been shown to be most specific for androgen deficiency.[1,2,5] The remaining symptoms are sensitive but non-specific, and are more commonly attributable to sleep restriction, energy deficit, mood disorder, or overtraining. A positive screen is an indication to evaluate, not a diagnosis, and the evaluation must consider those alternatives in parallel.

Symptom questionnaires validated in civilian populations perform poorly as standalone screening instruments; the ADAM instrument reported 88 percent sensitivity against 60 percent specificity in its original validation.[21] Both the Endocrine Society and the AUA advise against their use to define treatment candidacy.[1,2] The instrument above is accordingly structured as a case-finding prompt within a broader clinical evaluation, and is not to be scored or applied as a diagnostic test.

Laboratory Testing

Laboratory testing will be obtained where the screening assessment is positive, or where a listed risk factor is present. Testing will not be obtained unless the pre-test conditions below are satisfied.

Conditions for Valid Testing

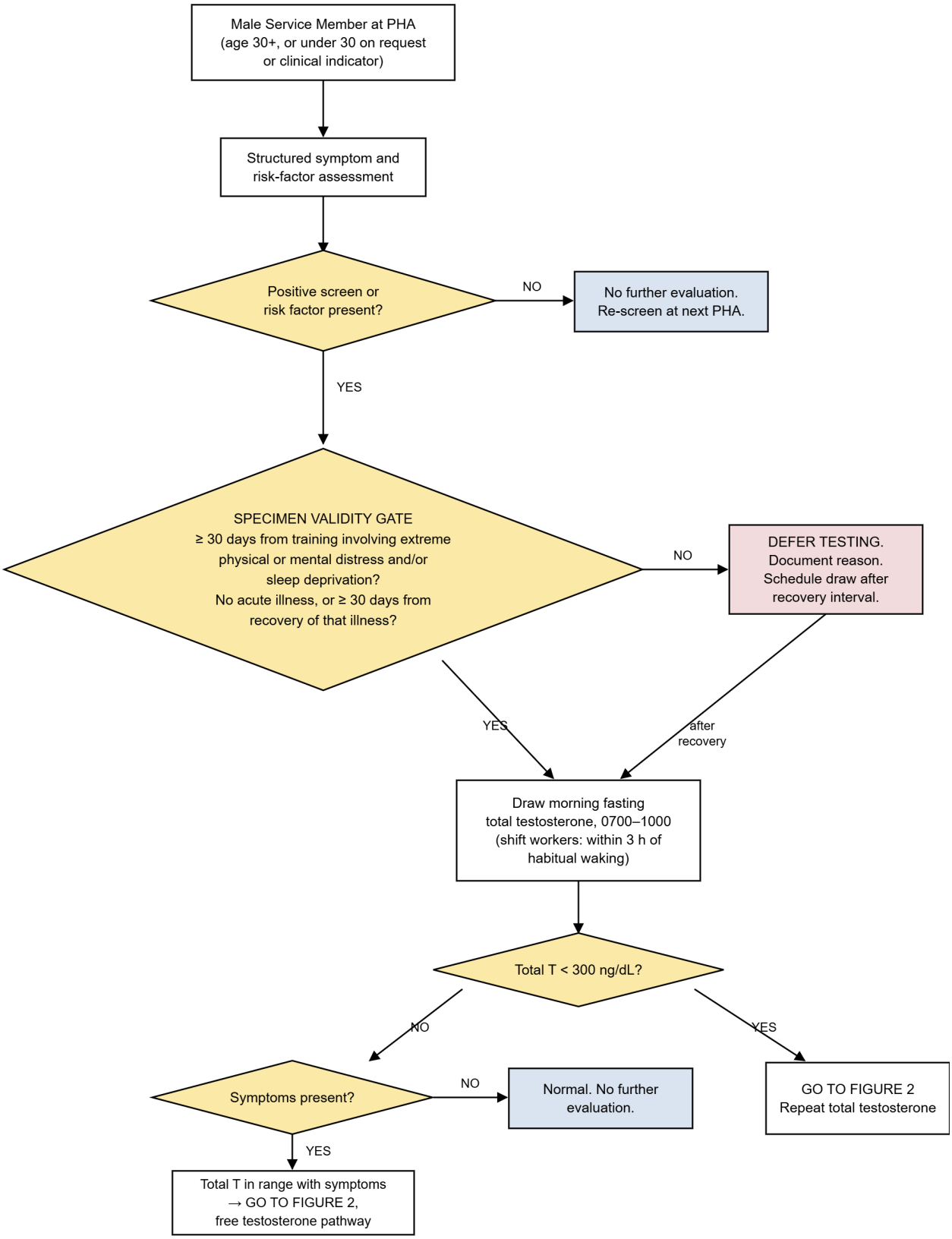
Testosterone concentrations vary with time of day, fasting state, acute illness, sleep, and energy balance. A specimen that does not satisfy the following conditions is not interpretable and will not be used to establish or exclude a diagnosis.

- Timing: drawn between 0700 and 1000. For Service members on night or rotating shifts, drawn within three hours of habitual waking following a normal sleep period, with the schedule documented.

- Fasting: the specimen is drawn fasting.
- Recovery: at least 30 days following training that includes extreme physical or mental distress and/or sleep deprivation.
- Illness: not during acute illness, and not within 30 days of recovery from that illness.
- Medication: current opioid, glucocorticoid, and anabolic steroid exposure documented before the draw.

The provider will affirmatively document that these conditions were met. Where a diagnosis rests on specimens obtained within 30 days of any of the conditions above, the diagnosis will be re-confirmed following an adequate recovery interval before therapy is initiated.

Figure 1. Screening and specimen validity.



DIAGNOSTIC EVALUATION

Initial Specimen

The initial test is total testosterone. Immunoassay is acceptable for initial testing. The decision limit for the initial specimen is 300 ng/dL.[2] A value at or above 300 ng/dL in a Service member whose screen was negative concludes the evaluation. A value at or above 300 ng/dL in a symptomatic Service member proceeds to free testosterone assessment below.

Confirmatory Specimen

No diagnosis will be made on a single specimen. Approximately 30 percent of men with an initial low value are normal on repeat testing.[1] A second specimen will be obtained on a separate day under the same pre-test conditions. LH and FSH will be obtained once, with this draw.

Free Testosterone and SHBG

Total testosterone misrepresents androgen status where SHBG is abnormal. Low SHBG (adiposity, insulin resistance, diabetes, glucocorticoids) yields a low total with preserved free testosterone. High SHBG (age, hyperthyroidism, hepatic disease, anticonvulsants, constitutional variation) yields the converse — a total within the reference range with a genuinely low free testosterone. That second group is missed by total testosterone alone: in the European Male Ageing Study, 8.3 percent of men had a normal total with a low free testosterone, and had significantly more sexual dysfunction, poorer physical function and slower gait speed than men normal on both.[19]

Obtain total testosterone and SHBG to calculate free testosterone where (a) a symptomatic Service member's total testosterone falls within the reference range, or (b) an SHBG-altering condition is present. Record the method used. The reference interval is 66 to 309 pg/mL across adult ages.[4]

Determining the Level of the Defect

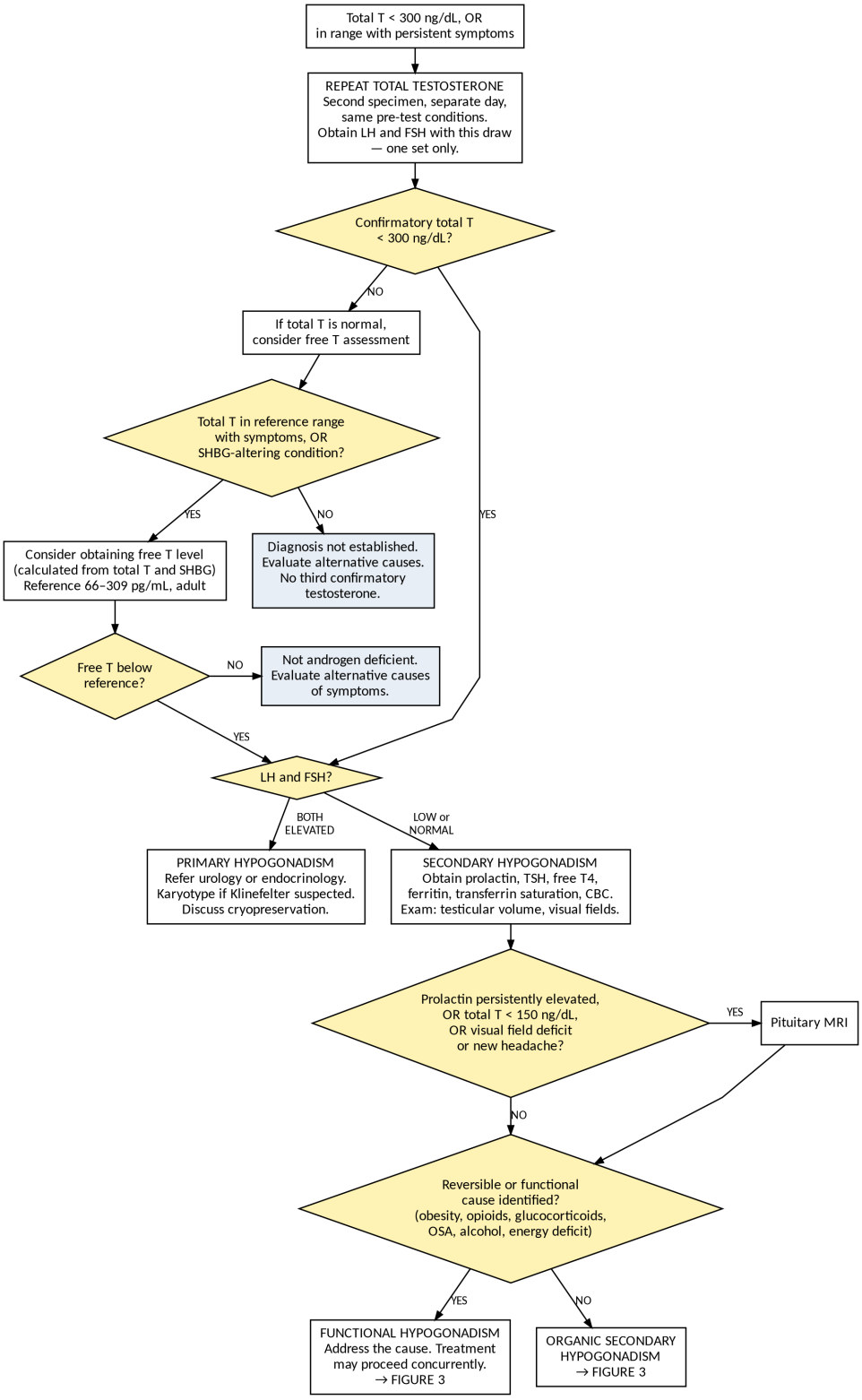
LH and FSH will be obtained with the confirmatory specimen. Elevated gonadotropins with low testosterone indicate primary hypogonadism and warrant referral to urology or endocrinology, with karyotype where Klinefelter syndrome is suspected. Klinefelter syndrome occurs in approximately 1 to 2 per 1,000 males, and an estimated 60 to 75 percent of affected men are never diagnosed.[20]

Low or inappropriately normal gonadotropins with low testosterone indicate secondary hypogonadism. The provider will conduct a focused examination including testicular volume and consistency, visual fields, and assessment for signs of systemic endocrinopathy, and will obtain prolactin, TSH and free T4, ferritin and transferrin saturation, and a complete blood count. Pituitary imaging is not routinely indicated; it will be obtained for persistently elevated prolactin, total testosterone below 150 ng/dL, visual field deficit, or new or worsening headache.[1,2]

Elevated Testosterone

A total testosterone above the reference range in a Service member not prescribed testosterone requires evaluation and is not to be recorded as an incidental finding. LH and FSH will be obtained. Suppressed gonadotropins with an elevated testosterone are the expected pattern of exogenous androgen exposure. Elevated gonadotropins with elevated testosterone, or an isolated elevation with normal gonadotropins, warrant endocrine referral.

Figure 2. Diagnostic evaluation.



Adapted from the American Urological Association Testosterone Deficiency Guideline (2018).[2]

MANAGEMENT

General Principles

Treatment is indicated for a Service member with a confirmed biochemical diagnosis and a compatible symptom profile. Treatment is not indicated on the basis of a laboratory value alone, nor on the basis of symptoms alone.[1,2,5,26]

Before any prescription, the provider will (a) identify and address reversible contributors; (b) determine and document the Service member's fertility intent; and (c) complete the informed consent discussion at Appendix B.

Reversible and Functional Causes

Where a reversible contributor is present, it will be addressed. Obstructive sleep apnea will be evaluated where indicated by symptoms or a positive screening instrument. Opioid and glucocorticoid exposure will be reviewed for taper or substitution in coordination with the prescribing service. Alcohol use, sleep, and energy availability will be assessed and addressed.

Addressing a reversible cause and initiating therapy are not mutually exclusive, and a reversible cause is not a reason to defer treatment of a symptomatic Service member with a confirmed diagnosis. The reversible contributor will still be managed to completion, and the need to treat still remains.

Adiposity-Associated Hypogonadism

Obesity warrants further evaluation for possible etiology of hypogonadism. Weight reduction raises total testosterone in proportion to the weight lost.[12] Weight management will be offered, including pharmacotherapy where indicated.

Patients will be offered lifestyle intervention for reversible causes, but treatment will not be withheld during this time. Requiring documented weight loss before permitting therapy converts a clinical recommendation into an access barrier and is not supported by this CPG.

Fertility Preservation and Gonadotropin-Based Therapy

Exogenous testosterone suppresses gonadotropin secretion and intratesticular testosterone, and reliably impairs spermatogenesis. Suppression is usually reversible: in pooled analysis, approximately 67 percent of men recovered a sperm concentration of 20 million/mL by 6 months, 90 percent by 12 months, and effectively all by 24 months following discontinuation.[14] Recovery is slower and less certain with prolonged exposure, higher doses, older age, and pre-existing testicular dysfunction, and persistent azoospermia, while uncommon, cannot be excluded.[28]

Fertility intent will be determined and documented before any prescription.

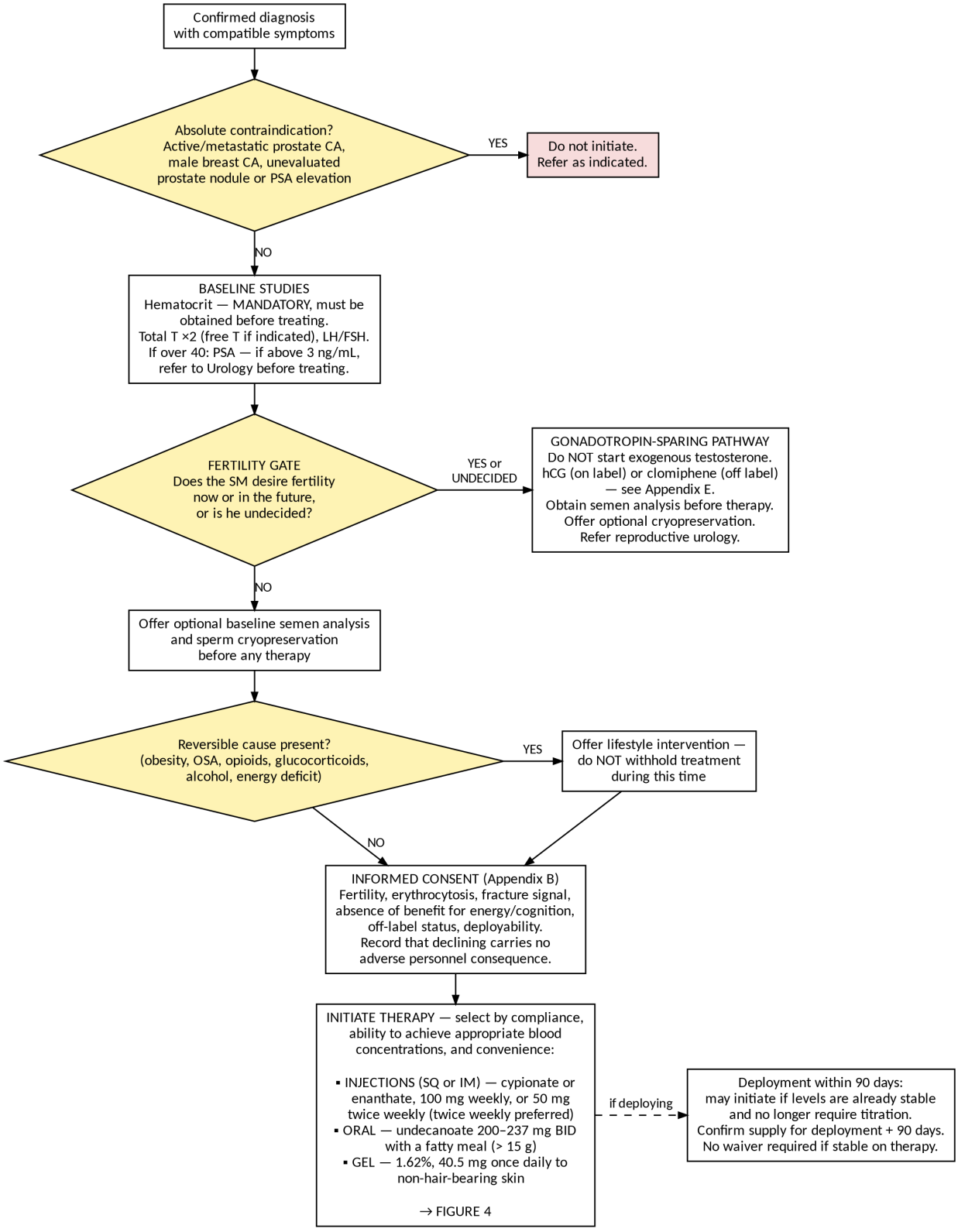
Where fertility is desired or is undecided, exogenous testosterone will not be initiated. Two options are available:

- Human chorionic gonadotropin (hCG), which stimulates Leydig cell testosterone production and maintains intratesticular testosterone and testicular volume. hCG is FDA-approved for hypogonadotropic hypogonadism in males.
- Clomiphene citrate, which raises endogenous LH, FSH and testosterone. Clomiphene is used off-label for this indication.

Appendix E governs the discussion of off-label use with the Service member.

A semen analysis should be obtained before starting therapy. In addition, sperm cryopreservation should be discussed (when appropriate) for any Service member desiring future fertility and considering testosterone therapy. Referral to reproductive urology will be offered if fertility is actively, or in the near future, being pursued.

Figure 3. Treatment pathway selection.



TESTOSTERONE REPLACEMENT THERAPY

Formulation Selection

Multiple formulations should be considered when offering testosterone therapy. Consider the Service Member's ability to comply with treatment, the appropriateness of the chosen product, and the patient's preference and convenience when selecting the type and dose.

Erythrocytosis risk is a property of formulation and dosing interval.. Reported mean increases: oral undecanoate 4.3 percentage points, short-acting intramuscular 4.0, transdermal gel 3.0, long-acting intramuscular undecanoate 1.6.[11] Short-acting injection at extended intervals is the highest-risk configuration.

Dosing

Injection therapy will consist of testosterone cypionate or enanthate, subcutaneous or intramuscular, with starting doses of 100 mg once weekly, or the weekly dose divided and administered twice weekly.[1,2] Divided twice-weekly administration can be advantageous because it reduces the peak-to-trough excursion that drives both symptom fluctuation and peak-associated erythrocytosis.[1,2,17]

Oral testosterone undecanoate is taken twice daily with a fatty meal of more than 15 grams. Starting doses are 200 to 237 mg twice daily.

Testosterone gel 1.62 percent is applied once daily, 40.5 mg, to non-hair-bearing skin, and titrated as necessary.

Appendix A addresses the formulations; each has a defined role and specific limitations.

Targets and Titration

Therapy will be titrated on the trough concentration, drawn before the next scheduled dose or on the day it is due. The trough is the concentration the Service member experiences for the longest portion of the dosing interval and is the value most closely related to persistent symptoms.

Target trough is 300 to 600 ng/dL. Where the trough is below 300 ng/dL, the dose will be increased. Where it is 600 ng/dL or above, the dose will be reduced. Within the target range, the dose will be maintained.

A Service member whose trough falls within the target range but whose symptoms persist will not be managed by reflexive dose escalation, nor by reflexive discontinuation. He will be evaluated for (a) a low free testosterone; (b) an unaddressed alternative cause of the presenting symptoms, including sleep disorder, mood disorder, energy deficit, thyroid disease, or anemia; and (c) improper adherence and administration technique. Where free testosterone is low despite an in-range total, individualized adjustment is appropriate and the rationale should be documented.

Monitoring

Baseline, before initiation: total testosterone (confirmed), free testosterone and SHBG as indicated, LH and FSH as indicated, hematocrit, and PSA if over 40. A baseline hematocrit is mandatory; therapy will not be initiated without one.

At 4 to 6 weeks, and every 6 months thereafter, clinicians will obtain a trough total testosterone, hematocrit, and a structured symptom assessment. After any dose or formulation change, follow-up for reassessment will occur at approximately 4 to 6 weeks. PSA will be obtained annually for men over 40 or at high risk for prostate cancer.

Service members will be referred to Urology for a PSA above 3.0 ng/mL, or an increase exceeding 1.0 ng/mL within 12 months.[1]

Where the target trough has been achieved and no meaningful symptom improvement has occurred by 6 months, the diagnosis will be reconsidered.

Erythrocytosis

Erythrocytosis is the most common adverse effect of testosterone therapy and is dose-, route- and interval-dependent. A baseline hematocrit is obtained before initiation.

- Baseline hematocrit above 50 percent: do not start therapy until the etiology of the elevated hematocrit is explained — for example obstructive sleep apnea, polycythemia vera, or tobacco use.
- On therapy, hematocrit above 52 percent: recommend blood donation or therapeutic phlebotomy, reducing the dose, or withholding testosterone.
- On therapy, hematocrit at or above 54 percent: stop therapy until the hematocrit is below 50 percent, and suggest blood donation or therapeutic phlebotomy. Resume at a lower dose once normalized, and re-evaluate for an alternative cause.

The 54 percent action threshold is derived by extrapolation from epidemiologic data on primary polycythemia and is not established by outcome studies in men receiving testosterone therapy. No prospective or randomized study has demonstrated that testosterone-associated erythrocytosis causes thrombotic events. It is nonetheless retained as a conservative action threshold pending better evidence, and the Service member should be so informed.

Other Risks and Adverse Effects

Cardiovascular. TRAVERSE (n=5,204, ages 45–80, all with cardiovascular disease or ≥3 risk factors) found no increase in major adverse cardiac events, 7.0 versus 7.3 percent (HR 0.96), and the FDA removed the class-wide cardiovascular boxed warning in February 2025.[7,15] The same trial found more atrial fibrillation (3.5 versus 2.4 percent, p=0.02), acute kidney injury (2.3 versus 1.5, p=0.04) and pulmonary embolism (0.9 versus 0.5). That population was older and at far higher cardiovascular risk than the Service members addressed here; neither its reassurance nor its adverse signals extend to men under 45 without qualification.

Other. Blood pressure elevation (measure at every monitoring visit),[15] acne, injection-site reaction, gynecomastia, edema. Counsel patients on topical formulations regarding secondary transfer: application site, covering, hand washing, and avoiding skin contact with women and children until washed.

Contraindications

Absolute: hypersensitivity to a formulation component; untreated or metastatic prostate cancer; male breast cancer; an unevaluated prostate nodule or PSA elevation pending workup; current desire for fertility (for exogenous testosterone specifically — see the fertility section).

Relative: baseline hematocrit above 50 percent pending evaluation; untreated obstructive sleep apnea; myocardial infarction within the past 6 months, acute coronary syndrome or stroke within the preceding 6 months; uncontrolled heart failure; thrombophilia or prior unprovoked venous thromboembolism; severe lower urinary tract symptoms; uncontrolled hypertension.

Discontinuation

Therapy will be discontinued where an adverse effect cannot be managed, or at the Service member's election. Where the target trough has been achieved and no meaningful symptom improvement has occurred by 6 months, the diagnosis will be reconsidered.

Discontinuation after sustained exposure produces a symptomatic hypogonadal interval while endogenous production recovers, and abrupt cessation without planning is itself a readiness harm. Where discontinuation is elective and not urgent, the dose will be tapered. The Service member will be counselled that recovery of the axis and of spermatogenesis may take 6 to 24 months.[14] Total testosterone will be reassessed following discontinuation. Where fertility is desired, referral for gonadotropin-based recovery therapy will be offered.

Figure 4. Titration and dose adjustment.

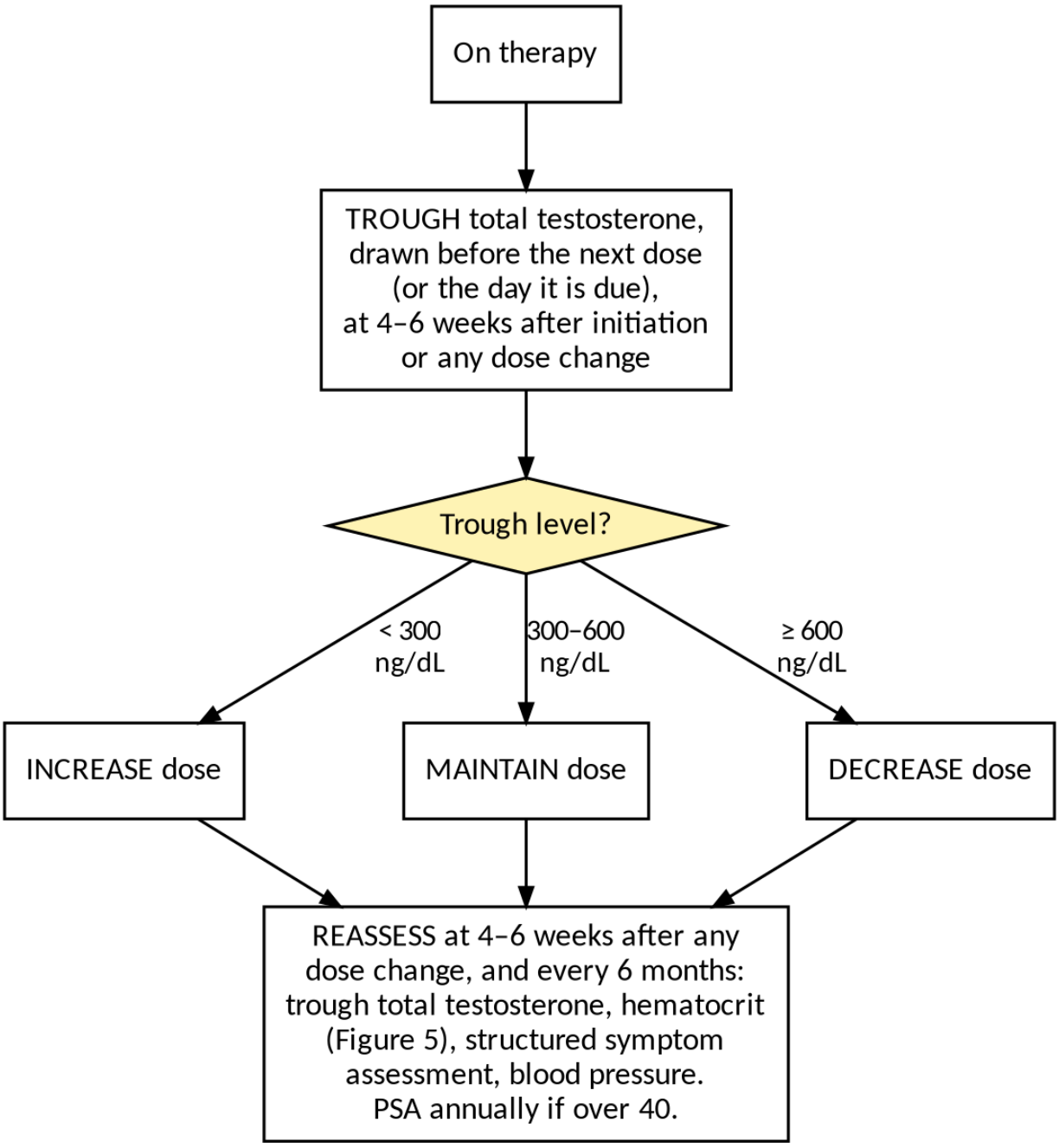
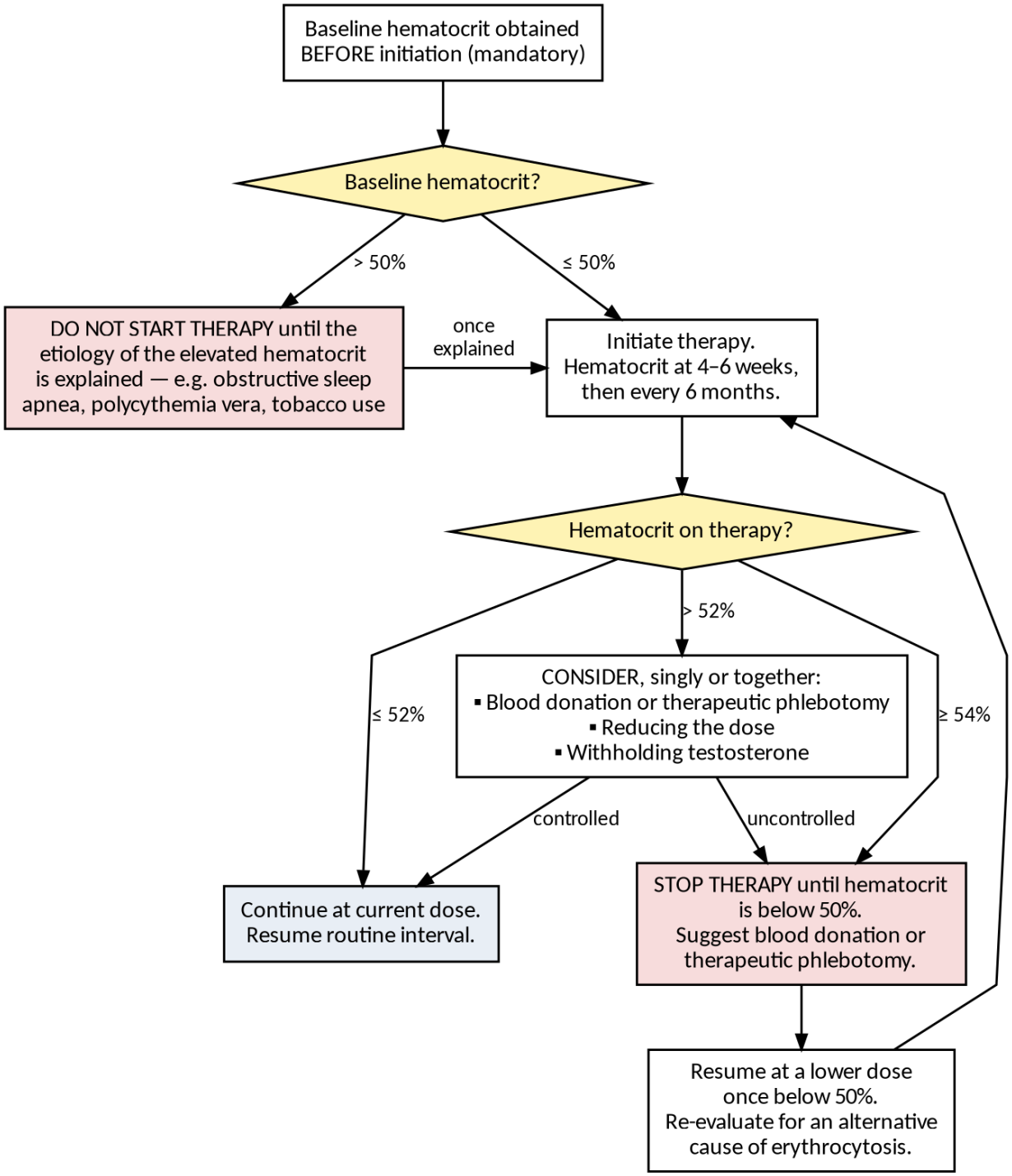


Figure 5. Erythrocytosis management on therapy.



DEPLOYMENT AND DUTY CONSIDERATIONS

Testosterone is a Schedule III controlled substance. Its use in the deployed environment raises supply, custody, storage, and continuity considerations that should be resolved before departure rather than in theater.

Deployment on treatment. Testosterone therapy may be initiated within 90 days of deployment, but continuation during deployment would require the 4–6 week follow-up assessment to demonstrate clinical stability and a testosterone level within the target range of 300–600 ng/dL. Once stability has been established, the patient would

then transition to the every-6-month monitoring schedule. A Service member who is stable on testosterone therapy should be deployable without requiring a waiver, depending on the formulation.

- Continuity of supply. Before departure, the prescribing provider will confirm a supply sufficient for the deployment plus 90 days, or a documented resupply pathway. Federal law limits Schedule III prescriptions to five refills within six months of issuance; a new prescription is required thereafter.[22]
- Storage and custody. Injectable testosterone requires controlled room temperature storage and controlled-substance accountability. Requirements are set out at Appendix C.
- Interruption. Where supply is interrupted, the Service member will be managed as a planned discontinuation and evaluated on return. Interruption is not a medical emergency but is a reportable event for performance improvement purposes.
- Aeromedical, dive, submarine and nuclear duty. Both the diagnosis and the therapy may bear on qualification for these duties. Determinations are made by the applicable Service authority under the governing instruction; this CPG does not alter those requirements.
- Medical readiness classification. Neither a diagnosis of testosterone deficiency nor stable maintenance therapy is, of itself, a basis for a duty limitation or a change in deployment status.

PERFORMANCE IMPROVEMENT (PI) MONITORING

Population of Interest

- All male Service members undergoing a Periodic Health Assessment at or after age 30, and on entry to the military.
- All male Service members with a recorded diagnosis of testosterone deficiency.
- All male Service members prescribed testosterone or gonadotropin-based therapy.

Intent (Expected Outcomes)

- Service members in the population of interest have a documented symptom and risk-factor assessment at the PHA.
- Laboratory specimens are obtained under documented valid pre-test conditions.
- No diagnosis is established on a single specimen.
- Fertility intent is determined and documented before any prescription.
- Service members with a reversible cause are offered lifestyle intervention without treatment being withheld.
- Service members on therapy have a trough testosterone and hematocrit at 4 to 6 weeks and every 6 months.
- The diagnosis is reconsidered where no symptom benefit has occurred by 6 months at target trough.
- Service members are not deployed on therapy without confirmed supply continuity.

Performance / Adherence Metrics

- Number and percentage of the population of interest with a documented symptom and risk-factor assessment.
- Number and percentage of initial specimens with documented valid pre-test conditions.
- Number and percentage of diagnoses supported by two morning fasting specimens.
- Number and percentage of prescriptions preceded by documented fertility-intent discussion.

- Number and percentage on therapy with trough testosterone and hematocrit recorded at 4 to 6 weeks and every 6 months.
- Number and percentage on therapy for more than 6 months without documented symptom benefit.
- Number and percentage with hematocrit above 52 percent and above 54 percent, and the intervention applied.
- Number and percentage of deployments on therapy with documented supply continuity.
- Rate of therapy interruption in the deployed environment.
- Number and percentage screened, tested, diagnosed, and treated — to establish program denominators.

Data Sources

- Military Health System GENESIS
- Defense Medical Surveillance System (DMSS)
- Pharmacy Data Transaction Service
- Documentation form at Appendix B

System Reporting and Frequency

Reporting will be performed annually, with an initial report at 12 months from publication. The initial report will establish program denominators — the number screened, tested, diagnosed and treated — which are not currently known and which no prior guidance projected.

Responsibilities

The MTF Chief Medical Officer is responsible for local familiarity, compliance, and PI monitoring under this CPG.

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APPENDIX A: DIAGNOSIS AND TREATMENT REFERENCE TABLES

Table A-1. Diagnostic pathway.

Finding	Action
Positive screen, age 30+	Confirm pre-test conditions are met. Obtain morning fasting total testosterone, 0700–1000, at least 30 days from training involving extreme physical or mental distress and/or sleep deprivation.
Total T ≥ 300 ng/dL, symptoms present	Obtain total testosterone and SHBG to calculate free testosterone. Reference 66–309 pg/mL, adult. Evaluate alternative causes in parallel.
Total T < 300 ng/dL	Repeat on a separate day under the same conditions. Obtain LH and FSH with this draw — one set only. No third confirmatory testosterone.
Low T, elevated LH/FSH	Primary hypogonadism. Refer to urology or endocrinology. Karyotype if Klinefelter suspected. Discuss cryopreservation.
Low T, low or normal LH/FSH	Secondary hypogonadism. Obtain prolactin, TSH, free T4, ferritin, transferrin saturation, CBC. Focused exam including testicular volume and visual fields.
Prolactin persistently elevated, or total T < 150 ng/dL, or visual field deficit	Pituitary MRI.
Obesity, workup otherwise unremarkable	Adiposity-associated functional hypogonadism. Offer lifestyle intervention; do not withhold treatment during this time.
Total T above reference range, not prescribed testosterone	Obtain LH and FSH. Suppressed gonadotropins suggest exogenous androgen exposure. Elevated or normal gonadotropins warrant endocrine referral.

Table A-2. Formulations, dosing and monitoring.

Formulation and route	Dose	Level monitoring	Notes
Injection — testosterone cypionate or enanthate, subcutaneous or intramuscular	100 mg once weekly, or 50 mg twice weekly (twice weekly preferred)	Trough, before the next dose or the day it is due. Target 300–600 ng/dL.	Lowest peak-to-trough excursion when divided twice weekly. Vial products given subcutaneously are off-label.
Oral — testosterone undecanoate	200–237 mg twice daily with a fatty meal (> 15 g)	Per product labeling	Requires a fatty meal for absorption. Blood pressure monitoring required.
Gel — testosterone 1.62%	40.5 mg once daily to non-hair-bearing skin; titrate as necessary	2–6 hours after application, 4–6 weeks after initiation or change	Lower hematocrit effect. Counsel on secondary transfer.
hCG	Per specialist direction	Total testosterone; semen analysis where fertility is pursued	FDA-approved for hypogonadotropic hypogonadism in males. Preserves intratesticular testosterone and testicular volume.
Clomiphene citrate	Per specialist direction	Total testosterone, estradiol, LH, FSH	Off-label for this indication. See Appendix E.

APPENDIX B: DOCUMENTATION AND INFORMED CONSENT FORM

Screening

- PHA date
- Symptom assessment completed (each item recorded)
- Risk factors present
- Screen result: positive / negative / declined

Pre-test conditions

- Draw time
- Fasting hours
- Days since field training, sustained ops, or documented sleep restriction
- Acute illness in preceding 30 days: Y/N
- Current opioid / glucocorticoid / androgen exposure

Laboratory

- Specimen 1: total T, date
- Specimen 2: total T, date
- Free testosterone, SHBG
- LH, FSH
- Baseline hematocrit (required)
- PSA if age- or risk-indicated

Diagnosis

- Classification: primary / secondary / functional / not established
- Reversible contributors identified and action taken

Before prescribing

- Fertility intent discussed and recorded
- Cryopreservation offered: Y/N/declined
- Off-label status discussed where applicable (Appendix E)
- Patient information sheet provided (Appendix F)
- Statement recorded that declining evaluation or treatment carries no adverse personnel consequence
- Deployability and duty implications discussed

Therapy

- Agent, dose, route, interval
- Target trough band
- Date of initiation

Monitoring

- 4-6 weeks after initiation of T therapy: trough T, HCT, symptom reassessment
- q 6-month: trough T, HCT symptom reassessment, (PSA annually in men over 40)
- Continue / adjust / discontinue, with rationale

Deployment

- Supply confirmed for deployment plus 90 days, or resupply pathway documented
- Storage and custody addressed
- Duty qualification review initiated where applicable

APPENDIX C: FORMULARY AND MATERIEL

Materiel and formulary requirements for implementation of this CPG, including in the deployed environment.

Pharmaceutical

- Testosterone cypionate 100 mg/mL and 200 mg/mL multi-dose vials
- Testosterone enanthate 200 mg/mL vials
- Testosterone enanthate subcutaneous autoinjector, 50/75/100 mg
- Testosterone undecanoate oral capsules
- Testosterone gel 1.62%
- hCG 10,000 units/ampule
- Clomiphene citrate 50mg tablets

Administration Supplies

- Insulin-gauge syringes (27–30 G, 0.5 inch) for subcutaneous administration
- 21–23 G drawing needles; 23–25 G intramuscular needles
- Alcohol prep pads; sharps containers; sharps disposal for field use
- Patient self-administration instruction materials

Storage, Custody and Accountability

- Controlled room temperature storage, 20–25 °C, excursions permitted 15–30 °C. Protect from light. Do not freeze.
- Schedule III controlled-substance accountability at all echelons, including deployed custody and disposition of unused product
- Deployment supply: quantity sufficient for the deployment plus 90 days, or a documented resupply pathway

Documentation

- Documentation and informed consent form at Appendix B
- Patient information sheet at Appendix F

APPENDIX D: TELECONSULTATION

Testosterone deficiency management requires access to endocrinology, urology and reproductive urology expertise that is not present at every military treatment facility and is not present in the deployed environment. Teleconsultation is the primary mechanism for closing that gap.

ROUTINE	URGENT	DIRECT PATIENT CARE
Global Teleconsultation Portal https://GTP.health.mil Diagnostic questions, titration, erythrocytosis management, fertility pathway selection	ADVISOR line 833-ADVSRLN (833-238-7756) / DSN 312-429-9089 Hematocrit ≥ 54% with symptoms, suspected thromboembolism, suspected exogenous androgen exposure requiring same-day guidance	Virtual specialty appointment per local policy Reproductive urology consultation for fertility-preserving therapy Endocrinology for primary hypogonadism and pituitary findings

APPENDIX E: INFORMATION REGARDING OFF-LABEL USES IN CPGs

PURPOSE

The purpose of this Appendix is to ensure an understanding of DoD policy and practice regarding inclusion in CPGs of "off-label" uses of U.S. Food and Drug Administration (FDA)-approved products. This applies to off-label uses with patients who are armed forces members.

BACKGROUND

Unapproved (i.e., "off-label") uses of FDA-approved products are extremely common in American medicine and are usually not subject to any special regulations. However, under Federal law, in some circumstances, unapproved uses of approved drugs are subject to FDA regulations governing "investigational new drugs." These circumstances include such uses as part of clinical trials, and in the military context, command required, unapproved uses. In addition, some command-requested unapproved uses may also be subject to special regulations.

ADDITIONAL INFORMATION REGARDING OFF-LABEL USES IN CPGs

The inclusion in CPGs of off-label uses is not a clinical trial, nor is it a command request or requirement. Further, it does not imply that the Military Health System requires that DoD healthcare practitioners use or consider it the "standard of care." Instead, the inclusion in CPGs of off-label uses informs the clinical judgment of the responsible healthcare practitioner by providing information regarding potential risks and benefits of treatment alternatives. The decision is for the clinical judgment of the responsible healthcare practitioner within the practitioner-patient relationship.

Balanced Discussion

Consistent with this purpose, CPG discussions of off-label uses specifically state that they are uses not approved by the FDA. Further, such discussions are balanced in the presentation of appropriate clinical study data, including any such data that suggest caution in the use of the product and specifically including any FDA-issued warnings.

Quality Assurance Monitoring

With respect to such off-label uses, the DoD procedure is to maintain a regular system of quality assurance monitoring of outcomes and known potential adverse events. For this reason, the importance of accurate clinical records is underscored.

Information to Patients

Good clinical practice includes the provision of appropriate information to patients. Therefore, each CPG discussing an unusual off-label use will address the issue of information to patients. When practicable, consideration will be given to including an appropriate information sheet in an appendix for distribution to patients, whether before or after using the product. Information to patients should address in plain language: a) that the use is not approved by the FDA; b) the reasons why a DoD health care practitioner would decide to use the product for this purpose; and c) the potential risks associated with such use.

Off-Label Uses Addressed in This CPG

The following uses discussed in this CPG are not FDA-approved for the indication described: subcutaneous administration of testosterone cypionate and enanthate vial products, and clomiphene citrate for male hypogonadism. Human chorionic gonadotropin is FDA-approved for hypogonadotropic hypogonadism in males. Each is discussed in the text with the supporting data and the associated limitations. The patient information sheet at Appendix F addresses these uses in plain language.

APPENDIX F: PATIENT INFORMATION SHEET

This sheet is provided to Service members who are considering or receiving testosterone or related therapy under this CPG. It is written in plain language and is intended to support, not replace, the discussion with your provider.

What this treatment is for

Testosterone therapy treats a confirmed deficiency that is causing symptoms. It is not a performance enhancer, and the evidence does not show that it improves energy, physical performance, or thinking in men whose levels are normal. If your levels are normal, this treatment is unlikely to help you and may cause harm.

Why we test the way we do

Testosterone levels change with time of day, sleep, food, illness, and hard training. A single low reading is often normal on a repeat test. That is why we test twice, in the morning, fasting, and only after at least two weeks have passed since training that involved extreme physical or mental stress or sleep deprivation. This protects you from being treated for something you do not have.

Effects on fertility

Testosterone shuts down your body's own production of sperm. Most men recover after stopping — roughly two-thirds within six months and about nine in ten within a year — but recovery can take up to two years and is not guaranteed. If you want children now or in the future, tell your provider before you start. There are other treatments that raise testosterone without shutting down sperm production, and sperm banking is available.

Effects on your blood

Testosterone raises the thickness of your blood. This is the most common side effect. We check it before you start, at four to six weeks, and every six months. If it gets too high we can lower your dose, change how often you take it, or you can donate blood or have blood drawn off. If it goes above a set level we will pause treatment until it comes back down.

Other risks

One large trial found a small increase in bone fractures in men taking testosterone, mostly from falls. The same trial found no increase in heart attacks or strokes, but did find more atrial fibrillation and a small increase in blood clots in the lungs. Testosterone can raise blood pressure; acne and injection site reactions are common and usually minor.

Some treatments are used off-label

Some of the medicines described here are prescribed for purposes the FDA has not formally approved. This is common and lawful in American medicine. Your provider will tell you which category your treatment falls into and why it is being recommended.

Your choice

Whether to be evaluated, and whether to be treated, is your decision. Declining evaluation or treatment carries no adverse personnel consequence. You may stop treatment at any time; tell your provider first so that stopping can be planned, because stopping suddenly can leave you feeling worse for a period while your body restarts its own production.

Before you deploy

If you are on treatment and about to deploy, talk to your provider well before you leave about your supply, how it will be stored, and what happens if you run out. Running out in theater is avoidable with planning.