Clinic Optimizers

Bio-Identical Hormone Replacement Therapy for Women

Integrative Wellness Guide

Bio-Identical Hormone Restoration Therapy (BHRT) can restore specific hormone levels to optimal levels reducing negative symptoms associated with hormone imbalance. A simple blood test will detect hormone levels and allow our physician to customize a treatment plan using bio-identical hormones prescribed through a local licensed compounding pharmacy. Our BHRT program provides continued physician monitoring along with medication refills at a very affordable cost. In addition, the staff is available to assist patients at any time during therapy at no additional cost.

Blood Test Monitoring Schedule

The following are the required blood tests and how to use them for clinical decision making. Additional tests may be added at your discretion or the patientõs request.

1. **Initial Blood Test – New Female BHRT Patient**
   Fasted, morning and well hydrated conditions:

   - ✓ CMP-14
   - ✓ CBC
   - ✓ Lipid panel
   - ✓ Testosterone f+t
   - ✓ Estradiol
   - ✓ Progesterone
   - ✓ DHEA-S
   - ✓ TSH
   - ✓ FSH
   - ✓ LH

2. **90-Day Follow up – 12wks after initial Rx (Can be requested at 4-6 weeks if desired)**
   Fasted, morning sample and well hydrated conditions:

   - ✓ Testosterone F&T
   - ✓ Estradiol, regular
   - ✓ Progesterone
   - ✓ DHEA-Serum (Note: Need serum ï NOT SULFATE ï if on topical DHEA cream, check DHEA ï sulfate if on oral DHEA)
   - ✓ TSH
   - ✓ CBC
   - ✓ CMP
   - ✓ Lipids (NMR Lipid recommended but additional cost)

3. **6 Month Follow up – Every 6 months while on BHRT** (Same as 90-day panel).

Individual patients may feel better at different ends of the target range, especially with testosterone. A conservative approach would be to begin by aiming for the low end of the target hormone range. Then slowly titrate the hormone dosage until response is adequate. Blood work and S/S must be monitored during titration.

Total Testosterone	**40-90ng/dl**
Estradiol	**Based on cycle/SS**
DHEA-S	**250-450ug/dl**
Pregnenolone	**80-150ng/dl**
IGF-1	**150- 300ng/dl**
Vitamin D3	**70 -100nmol/ml**

****Target Hormone Ranges for Women**

4. **Additional blood tests to suggest:**

Dihydrotestosterone (DHT)	If experiencing acne or hair loss. Also, check if she has low libido even after starting testosterone
Pregnenolone	If experiencing possible adrenal disorder, fatigue, stress, and cognitive decline
Salivary Cortisol- 4 tube	Most accurate cortisol test
IGF-1	To check growth hormone function. Also, check in patients taking Sermorelin
Vitamin D3	Many patients are found to be deficient
NMR Lipid Panel	Substitute for regular lipid panel

5. Why is blood work required twice per year?

One of the purposes behind drawing blood for analysis is to provide our physician a means to compare how you are responding to therapy with your hormone blood levels and other important indicators of your health. This information allows the physician to make appropriate adjustments to your regimen, that not only improve how you are feeling, but minimize any side effects and risks with treatment. The laboratory analysis of your blood will also provide a comparison with initial blood work and provide data that will aid in the development of your treatment plan.

***Notes:** Follow-up blood testing and lab review are required **every 6 months** for all patients undergoing the various forms of HRT. First time patients are required to **follow up at 90 days** after starting therapy so that response can be analyzed, then every six months thereafter. In some cases, the medical doctor or nurse may want to see specific lab tests more frequently if there is a need for closer monitoring. This will be discussed with the patient during their consultation. When changing hormone medications during therapy, a follow up may be warranted to confirm that the change in dosage/medication is responding well.*

6. Follow-up Lab review:

a. 45-60m Follow Up Consultation with MD, Mid-Level, or RN

***Notes:** Be sure to tell all new patients that they receive a lower consultation price once they become patients. Follows up can be conducted by the doctor, PA, or head RN, as deemed by the medical director. The patient may choose unless the prescribing physician specifically notes otherwise. Always read previous notes to determine follow up requirements. Take the time to explain to each patient how our system works: the doctor reviews all notes and updates entered in to their chart by the PA, RN or MA each day and can/will make changes if needed. Many patients are comforted by this extra layer of oversight.*

7. Physical Examination:

A Physical Exam is required once per year, or every 12 months while on TRT. Clinical staff will monitor and make sure the PE has been completed prior to continuing treatment.

Medication Protocol & Dosage

Basic Protocol:

For women who complain of decreased libido, depressed mood, and decreased energy; and testosterone is either low or low normal, then testosterone alone should be used as a first line treatment. Alone in this case means without the use of estrogen. If patient complains of hot flashes, night sweats, or vaginal dryness, then consideration for using estrogen should be made. In determining whether to use estrogen, the severity of her symptoms and age of the patient should be considered. A younger patient who has not reached menopause and who is under the age of 50; as a rule, should be treated with testosterone alone to alleviate the symptoms of mild estrogen deficiency. In these cases, it is possible that testosterone therapy alone will be converted to the necessary estrogen in approx. 50% of the cases (Ref. Dr. Rand McClain). It is best to complete 6-12 weeks of TRT alone before adding estrogen and progesterone. Most complications with HRT that are possible occur with the use of estrogen, it is preferable to avoid estrogen use if possible.

Since BHRT in women is typically done trans-dermally via the use of topical creams/gels, there is a variability of absorption and therefore oftentimes more difficulty in titrating dosages appropriately. Topical BHRT hormones can be combined into one cream which helps reduce medication cost and provides convenience for the patient. When first prescribing BHRT be sure to separate the hormones so that individual hormones can be titrated accurately at follow up. (See Appendix 7 for more information on Hormone Deficiency in Women).

Medications:

1. **Testosterone 10mg/ml – 20mg/ml Topical Cream:** Starting Dose at 5mg-10mg daily.

Instructions: Titrate up 25% every two weeks based on symptoms. Do not increase dosage sooner than every two weeks to allow the hormone level to establish. If testosterone is going to be used vaginally, be sure to only use Versa base or Lidoderm compounded creams. Alcohol based gels will cause vaginal dryness and pain. This must be indicated on the prescription. Dosages will range between 2.5mg-25mg daily depending on how well the body absorbs the hormone. Be sure to consider labs for target range of 40ng-120ng (or >30), symptoms, and side effects before increasing the dosage. For females that desire a faster time to results and

resolution of symptoms, a higher daily dose of 10mg-20mg can be used for the first month to help saturate the patientôs system with testosterone and thereafter initial a lower dosage and titrate up.

Target Lab Range for Total Testosterone: 40-150ng with improvement of symptoms. HOWEVER ï symptoms and side effects should drive goal range for the skilled practitioner and some women require higher or lower levels for symptomatic improvement and side effect profile.

2. **Bi-Estrogen (Bi-Est) 5mg/ml Topical Cream:** Starting Dose is 1.25mg per day (1/4ml).

The highest dosage of estrogen that may be required is 10mg daily. Titrating the dose of estrogen must be done carefully every two weeks until reaching 1ml. Titration should increase by 1.25mg (1/4ml) every two weeks. Follow up labs will confirm estradiol levels. If the patient is currently taking an oral estradiol or similar estrogen and wants to switch to Bi-Est topical cream, the typical conversion from oral to transdermal would be to round to the closest dosage. For example, if the patient is using 1mg oral estradiol as part of her current estrogen replacement therapy, then we will use 1.25mg in a transdermal Bi-Est cream. The patient would continue taking her oral estrogen for 5 days after starting topical Bi-Est. After 5 days of using both, the oral and transdermal cream, the patient would only continue to use the transdermal Bi-Est**.**

Once a transdermal Bi-Est dosage is effective at eliminating symptoms and signs, then each month the dose of Bi-Est is reduced by 1/4ml until the S/S of estrogen deficiency begin to recur. At such time, increase Bi-Est by 1/4ml. No more titration is required until the patient complains of signs and symptoms of estrogen deficiency. **Bi-Estrogen breakdown-** For estrogen replacement therapy a combination of Estriol 80% and estradiol 20% is used and is called Bi-Estrogen, or Bi-Est.

3. **DIM 100mg capsule-** DOSAGE: 100mg by mouth per day.

All women who are using estrogen must also use DIM, also known as diindolylmethane. DIM is effectively used to stop the conversion from non-harmful to harmful estrogens. If a woman refuses to take DIM, we must document in the chart that we recommend she take DIM but patient refused.

4. **Progesterone 20% topical cream-** Starting Dose**:** 50mg (1/4ml) before bedtime.

   If the patient complains of PMS, a trial of progesterone can be used. The typical protocol is to begin with a total of 100mg daily of transdermal progesterone 7 days prior to start of menstrual cycle. This can be done in addition to oral progesterone if needed to treat symptoms.

5. **Progesterone compounded capsules-**

   Typically, these capsules come in 25mg-200mg dosages from our compounding pharmacy. The typical oral dosage is the same as the topical, 50mg-200mg before bedtime. Start with 50mg before bed and titrate by 25mg at each lab review until desired effect.

6. **DHEA topical or capsule-**

   If a woman has low normal or below normal levels of DHEA, a typical dose, which will resolve a deficiency and put the patient in a high normal DHEA blood concentration; is roughly 10mg per decade of age. However, most women do well on 20mg-30mg of DHEA. The dosage is the same for either capsule or topical cream.

7. **Pregnenolone Topical or Capsule-** DOSAGE: 50mg-150mg either by capsule before bed or trans-dermally before bed.

   If the patient is complaining of low concentration, memory loss, and cognitive decline; it should be noted whether a patientôs pregnenolone is at optimal levels or not. It must be explained to the patient the S/S of pregnenolone deficiency are less obvious and therefore more difficult to notice clinically, and that pregnenolone is responsible for maintaining cognition and fending off dementia.

8. **Omega-3 (Fish Oil)- Available OTC but quality varies:**

   A minimum of 2g per day of omega-3 should be recommended for aging women. Omega-3 fatty acid is used to lower elevated Triglycerides and improve cholesterol. It has been found to reduce high Triglycerides with such effectiveness that the FDA has approved it for lowering Triglycerides. Supplementing with Omega-3 has been found to increase HDL (good) cholesterol and lower VLDL (Bad) cholesterol, reducing risk factor for heart disease. Omega-3 appears to also help reduce inflammation. Omega-3 is contraindicated in patients already using a blood thinner such as Coumadin (aka Warfarin), Plavix, or baby aspirin. In

this case, the patient must get his physician who is prescribing the other blood thinner or blood thinners to approve the use of omega-3 as the use of Omega-3 will alter, if not eliminate the need for other blood thinners. Optimal omega-3 dosing for a patient with abnormal lipids and elevated triglycerides is 3,000-4,000mg daily.

9. **Vitamin D3- Compounded capsule 25,000iu or 50,000iu. OTC available for 5,000iu or 10,000iu.**

   Establish deficiency with a blood test prior to supplementation. 25,000iu titrated to 50,000iu taken once per week by mouth in capsule form. If daily dosing is desired, start with 5,000iu per day and increase until D3 levels are optimal as verified through a blood test. The maximum daily dosage of vitamin D3 is 10,000iu per day.

Treating Side Effects for Women on BHRT

In women experiencing androgenic side effects such as facial hair growth, clitoral enlargement, acne, or voice changes; the first change should be to reduce the level of testosterone given. Once testosterone has been reduced to the point of non-therapeutic levels, or D/C altogether, then spironolactone can be used to reduce androgenic side effects. Spironolactone starting dosage is 25mg each morning and is increased by 25mg each morning per week until symptoms resolve. Up to a dose of 100mg per morning can be used. Always remember to warn the patient not to use supplemental potassium when using spironolactone noting the possibility of heart failure of potassium is in excess, and as always, document this discussion including warnings in the notes. Remember that spironolactone is a diuretic; meaning that it causes the body to expel water, and should be taken in the morning.