

BIOIDENTICAL HORMONE REPLACEMENT THERAPY

PERIMENOPAUSE: This is the period of the years of a woman's life prior to menopause that encompasses the change from normal ovulatory cycles to cessation of menses. It is marked by irregularity of menstrual cycles. Ovulation occurs less and less as she runs out of eggs in the ovaries. The ovaries stop working. But estrogen levels remain fairly stable until about 6-12 months before actual menopause. When women are in the 40's, failure to ovulate (anovulation) occurs more and more frequently. For 2-8 years prior to menopause, menstrual cycle length increases.

MENOPAUSE: This is defined as that point in time when permanent cessation of menstruation occurs following the loss of ovarian activity. Contraception is necessary until one year of no periods.

SYMPTOMS OF MENOPAUSE: Apart from changing periods, women may experience what some have called the 'Seven Dwarfs of Menopause' – Itchy, bitchy, Sweaty, Sleepy, Bloating, forgetful, and All Dried Up. [S. Somers, *The Sexy Years*]. You may also get increased leaking of urine, bladder infections, and facial hair. Many women also experience increased hair loss which can be quite distressing for them and this may begin in the perimenopause.

BENEFITS OF BIOIDENTICAL HORMONE REPLACEMENT: Bioidentical hormone replacement involves giving your body additional amounts of estradiol (the most important of the three human estrogens. The others are estriol and estrone), testosterone, and progesterone. When these hormones are replaced in men and women whose levels are low, the following benefits occur:

- Relief of all or most symptoms of menopause
- Protection against osteoporosis
- Reduced risk of breast cancer
- Reduced risk of colon cancer
- Reduction in abdominal fat
- More energy
- More mental clarity
- Stronger bones and muscles
- Less depression and anxiety
- More stamina
- Normalization of libido (sex drive)
- Reduction in 'menstrual migraines' in women
- Enhanced erectile ability in men
- Prostate protection in men

POSSIBLE ADVERSE EFFECTS (mainly women):

- Vaginal bleeding is not uncommon
- Breast tenderness
- Increase in emotional sensitivity
- Could trigger more headaches instead of fewer
- Sleepiness (progesterone)
- Pelvic pain
- Rash from patches or infection at pellet site

‘I ALWAYS THOUGHT THAT HORMONES CAUSE CANCER’: The only real concerns regarding cancer are two things. One is that if you already have an untreated breast cancer that is “estrogen-receptor positive”, adding more estrogen to your blood may accelerate its growth. But we now know through a number of studies that BHRT does NOT increase the risk of breast cancer, and that it may, in fact, REDUCE your risk of breast cancer. For example, one retrospective study of 986 women on subdermal hormone pellet implants for ten years, there were NO NEW CASES of breast cancer, when there should have been over 20 cases based on statistical risk.

The second concern is that if you give estrogen to a woman who has not had a hysterectomy, and you don’t also give some type of progesterone on a regular basis, she could develop a thickened lining of her uterus (endometrium) and that could lead, in a pretty small percentage of cases, to a low grade form of endometrial cancer. In women who did develop that type of cancer, a hysterectomy is curative. In fact, the death rate in women with that type of cancer is no higher than the normal population.

PREFERRED ROUTES OF HORMONE DELIVERY

All your reproductive life, your hormones have been delivered directly into your bloodstream. Therefore, that is the preferred delivery route. That means either through the skin, under the tongue, or subdermal pellet implants. Taking hormone pills by mouth is NOT the best delivery system, because the hormone must first pass through the liver, where most of it is removed. And in the process of removal, there is a negative effect on clotting factors, which is why there is an increased rate of blood clots and stroke. With oral hormones, you may also get nausea, jaundice, or gallbladder problems.

IDOLE-3-CARBINOL

All women who are on BHRT should take a supplement of Indole-3-carbinol (Meta-I-3C). These derivatives of cruciferous vegetables promote the healthy metabolism of estrogen and reduce the risk of negative side effects.

FREQUENTLY ASKED QUESTIONS

WHAT ARE HORMONE PELLETS MADE OF? The pellets are derived from soybeans, and are biologically identical to human forms of estradiol and testosterone. There is also a small amount of magnesium stearate added to the prepelletized powder to help it flow better during the pellet making process. The pellets are specially manufactured by select compounding pharmacies using strict manufacturing standards. These pharmacies are accredited and monitored by the Pharmacy Compounding Accreditation Board, DynaLabs CQI Partner Program, and Formulary, Quality and Regulatory Committee. The pellets are completely biodegradable under the skin leaving no residue whatsoever.

HOW OFTEN WILL I NEED THEM INSERTED?

Typically from 3-6 months. Occasionally 'booster' doses can be given up to two months following the insertion if levels are not high enough.

DOES IT MATTER WHAT TIME OF MY CYCLE OR DAY TO HAVE MY BLOOD TESTED? For women, it's best to have your hormone levels checked a week prior to, during, or after your period at any time of the day. For men, it is best to have your testosterone levels checked early in the morning when the levels are highest.

HOW WILL I KNOW WHEN IT'S TIME FOR MORE PELLETS? People can generally tell when it's time for more pellets by how they feel. If you feel they've worn off before a 3 month time period, your blood levels should be rechecked to see where you are. If it's been longer than 4 months, you can get more pellets without another blood test. Between 3 and 4 months is on a case by case basis.

I GET HORRIBLE HEADACHES AROUND THE TIME OF MY PERIOD. WILL THIS HELP? Yes! Subdermal estradiol pellet implants have had great success in dramatically reducing hormone related migraine headaches.

ARE THERE ANY SIDE EFFECTS AND/OR COMPLICATIONS? Unlike other forms of hormone therapy, there are very few side effects and they are usually transient. You could get some breast discomfort, nipple tenderness, bloating, and rarely a pellet site could get infected or the pellet could come out. As with hormone therapy in general, some women get a return of menstrual type bleeding particularly if the progesterone is given cyclically rather than continuously. Usually, this bleeding is easily managed by adjusting the doses of the pellets or the progesterone. With the testosterone pellets in women, there are occasional incidents of increased or darker hair growth or mild acne, but these issues are generally minor and easily managed.

HOW LONG WILL IT TAKE FOR THE PELLETS TO TAKE EFFECT? 24-72 hours. Results are almost always seen within a few days to weeks.

IF I AM A WOMAN, DO I STILL NEED ESTROGEN AFTER MENOPAUSE?

Bioidentical estrogen is the most important hormone for a woman to protect her against loss of teeth and osteoporosis.

I HAVE NO LIBIDO. WILL THIS HELP? For men and women, good hormone balance will usually greatly improve your sexual desires.

DO I NEED OTHER MEDICATIONS? Unless the uterus has been removed, women will also need **progesterone**, to protect the uterine lining from excessive buildup. This is given either as drops under the tongue, skin gel, or pills, usually in a cycled fashion.

DOES MY INSURANCE COVER THIS? Insurance coverage varies greatly. It's best if you contact your own insurance plan and ask if they cover this procedure. The CPT code used for the insertion is 11980. The pellets themselves (A4550) are compounded and therefore do not have an NDC number, which insurance generally asks for.

WHAT IS THE COST? \$200.00 insertion plus pellets (\$35.00 - \$50.00 each) **paid at the time of service.** Insurance will not be billed.

If you choose to have us try to bill your insurance the cost is \$380.00 insertion and tray. Pellets (\$35.00 - \$50.00 each) for females are not billable. In addition, **we do not accept any insurance discount for this procedure.**

Prices are subject to change without prior notification.

WHAT DO I NEED TO DO TO GET STARTED?

- 1) Make an appointment for a consultation with one of our providers. This visit is mandatory for the provider to review your records, obtain or review necessary bloodwork and perform any necessary examination.
- 2) Mammogram and pap smear are required to be done within one year. Insertions will not be performed unless these results are in your chart or you have a signed waiver.
- 3) Read thoroughly and sign the consent form.
- 4) Once all the bloodwork, pap and mammogram results have been reviewed and discussed and it is determined that pellets are right for you, an insertion appointment may be made. Our physician assistants do the insertions.

NOTE: Insurance will not pay for a consultation AND insertion on the same day.

3-4 weeks after your insertion you will need post pellet bloodwork to record your hormone levels. Once your pellet dose is perfected you will not need bloodwork after each insertion more than once a year.