### **Contraceptive Management of Patients with Risk Factors**

Family planning clients with certain risk factors must have their contraceptive options balanced with the need to prevent an unintended pregnancy which can carry risks for both the mother and the baby. Various risk factors put a woman at increased risk for thromboembolic phenomenon. The Alabama Department of Public Health (ADPH) family planning protocol seeks to address these risks. In some women, estrogen containing methods are clearly not the best choice and may be contraindicated. In contrast, progestin-only methods carry much less risk regarding thromboembolic events and can be considered if the woman is counseled thoroughly and is aware of and accepts the potential increased risks associated with progestin-only methods. This counseling should be documented in the patient's medical record. Consults in this document refer to the nurse practitioner or nurse who seeks guidance with their collaborating physician or back-up physician in phone and/or written formats. Any phone consult warrants a followed written consult.

Patients should be counseled to notify all healthcare providers of any hormonal method used. If the patient does not have a medical home, counsel her to obtain a primary medical doctor (PMD). As described in the Nurse Practitioner Collaborative Disclaimer at the beginning of this manual, ADPH family planning protocol is derived from evidence based standards of care, relying on documents from entities such as the Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report, The 2016 U.S. Medical Eligibility Criteria for Contraceptive Use (U.S. MEC) and the American College of Obstetricians and Gynecologists (ACOG). The following section entitled "Contraceptive Management of Patients with Risk Factors" has been developed for NPs, utilizing this evidence based consensus-driven guidelines. The U.S. MEC Guidelines which consist of medical eligibility criteria for contraceptive use provide the basis for the hormonal methods recommended for the specific medical condition. The goal of these recommendations is to remove unnecessary medical barriers to accessing and using contraception, thereby decreasing the number of unintended pregnancies.

#### How to use this document

### Categories of Medical Eligibility Criteria for Contraceptive Use

- **1** = A condition for which there is no restriction for the use of the contraceptive method.
- **2=** A condition for which the advantages of using the method generally outweigh the theoretical or proven risks.
- **3=** A condition for which the theoretical or proven risks usually outweigh the advantages of using the method.
- **4=** A condition that represents an unacceptable health risk if the contraceptive method is used.

#### **Abbreviations**

Cu-IUD - Copper

LNG-IUD - Levonorgestrel

Implant - Nexplanon

DMPA - Depo Provera

POP - Progestin only pill

CHC - Combined hormonal contraception/Pills, Ring, Patch

I/C - Initiation of method/Continuation of method

---- Method not appropriate for use

#### **Appendices**

- Appendix A: Low Risk Patients with Breast Masses
- Appendix B: Recommendations based on Multiple Risk Factors
- Appendix C: Seizures/Anticonvulsant Therapy
- Appendix D: Polycystic Ovarian Syndrome (PCOS)
- Appendix E: Indications for Extended Use of Hormonal Methods
- Appendix F: Antiretroviral Therapy (ARV) List
- Appendix G: How to be Reasonably Certain that a Woman is Not Pregnant
- Appendix H: Identifying Migraine Headaches Tool/Forms

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| 1 RISK FACTOR      | Cu-<br>IUD | LNG-<br>IUD | Im<br>plant | DMPA | POP | СНС | CONSULT<br>(* = Consult) | COMMENTS $(\sqrt{=\text{Comments}})$  |
|--------------------|------------|-------------|-------------|------|-----|-----|--------------------------|---|
| Age√               |            |             |             |      |     |     |                          |   |
| Menarche -18 years | 2          | 2           | 1           | 2    | 1   | 1   |                          | Women who have metabolic bone disease or chronic corticosteroid use (>6 months duration) require a <b>phone consult.</b> Most studies show that women lose bone mineral density during DMPA use and it is unclear if women with long durations of DMPA regain their baseline levels. Any changes in health status including medications may change the appropriateness of DMPA. |
| 19-34 years        | 1          | 1           | 1           | 1    | 1   | 1   |                          |   |
| 35-49 years        | 1          | 1           | 1           | 1    | 1   | 1   |                          |   |
| 50-54 years        | 1          | 1           | 1           | 4√   | 2   | 2   |                          | Most studies show that women lose bone mineral density during DMPA use and it is unclear if women with long durations of DMPA regain their baseline levels. Any changes in health status including medications may change the appropriateness of DMPA.  |
| ≥55 years          | 4          | 4           | 4           | 4    | 4   | 4   |                          |   |

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| Anatomical abnormalities                               |            |             |             |      |     |     |   |  |
| Distorted uterine cavity - (fibroids, bicornate, etc.) | 4          | 4           | 1           | 1    | 1   | 1   | Written Consult<br>and Referral for<br>new finding of<br>enlarged uterus. |  |
| Antimicrobials   | 1          | 1           | 2√          | 1    | 3√  | 3√  |   | Rifampin and Rifabutin decrease contractive effectiveness. DMPA preferred. Back-up method recommended.   |
| Anemias√   |            |             |             |      |     |     |   | See Abnormal Findings protocol   |
| Thalassemia  | 2          | 1           | 1           | 1    | 1   | 1   |   |  |
| Sickle Cell Disease√                                   | 2          | 1           | 1           | 1√   | 1   | 2*  | Phone Consult (due to increased coagulation activity)                     | DMPA method preferred.  DMPA may prevent painful sickling crises (in which red blood cells clog blood vessels).  |
| Iron-Deficiency√                                       | 2          | 1           | 1           | 1    | 1   | 1   |   | All anemias need referral if unexplained and undiagnosed Hemoglobin <10.  Increased risk colon cancer >45 years African American patients, FIT testing indicated, see FIT protocol. Recheck Hgb 6-8 weeks. |

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| Breast disease√  |            |             |             |      |     |     |                                    | See Abnormal Findings Protocol   |
| Undiagnosed mass*√   | 1          | 2           | 2           | 2    | 2   | 2   | Phone Consult if patient >25 year. | <ul> <li><a href="mailto:specific black"></a> years generally ok to initiate/continue method, up to 3 month supply. See Appendix A.</li> <li>&gt;25 years, phone consult indicated.</li> </ul>                 |
| Benign breast<br>disease or family<br>history of cancer√             | 1          | 1           | 1           | 1    | 1   | 1   |                                    | Annual mammography recommendations starting no later than ten years before the age of the earliest diagnosis in the first degree relative (but not earlier than age 25 and not later than age 40).             |
| Breast cancer current√   | 1          | 4           | 4           | 4    | 4   | 4   |                                    | Most breast cancer is hormonally sensitive.  |
| Breast cancer past   | 1          |             |             |      |     |     |                                    |  |
| Breastfeeding  |            |             |             |      |     |     |                                    |  |
| <21 days postpartum  |            |             | 2*          | 2*   | 2*  | 4   | <b>Phone Consult</b>               |  |
| 21-<30 days<br>postpartum with or<br>without risk factors<br>for VTE |            |             | 2*          | 2*   | 2*  | 3*  | Phone Consult                      | VTE Risk Factors: age ≥35, previous VTE, thrombophilia immobility, transfusion at delivery, peripartum cardiomyopathy, BMI ≥ 30kg/m², postpartum hemorrhage, post cesarean delivery, preeclampsia, or smoking. |
| 30-42 days<br>postpartum with risk<br>factors for VTE                |            |             | 1*          | 1    | 1√  | 3*  | Phone Consult                      | Other risk factors for VTE increase the classification to a higher category 4. All postpartum patients will need postpartum exam documentation prior to dispensing.  |
| 30-42 days<br>postpartum without<br>risk factors for VTE             |            |             | 1*          | 1    | 1√  | 2*  | Phone Consult                      | All postpartum patients will need postpartum exam documentation prior to dispensing.   |
| >42 days postpartum  |            |             | 1*          | 1    | 1√  | 2   | Phone Consult                      | Referral for IUD and left to the discretion of the referring provider.   |

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|--|------------|--------------|--------------|--------------|------------------------------------|-----|---|--|
| Peripartum cardiomyopathy                                  |            |              |              |              |                                    |     |   |  |
| Normal or mildly impaired cardiac function < 6 months      | 2          | 2            | 1*           | 1            | 1√                                 | 4   | Phone Consult   | POPs up to 3 month supply. Increased risk of fluid retention; increased risk of cardiac arrhythmia.  |
| Normal or mildly impaired cardiac function $\geq 6$ months | 2          | 2            | 1*           | 1            | 1√                                 | 3*  | Phone Consult<br>for Implant<br>Written Consult<br>for CHC  | Up to 3 month supply Higher incidence cardiac arrhythmias.   |
| Moderately or severely impaired                            | 2          | 2            | 2*           | 2            | 2√                                 | 4   | Phone Consult   | POPs up to 3 month supply.  New York Heart Association Functional Class III or IV: patients with marked limitation or bed rest.  |
| Ischemic heart<br>disease                                  |            |              |              |              |                                    |     |   |  |
| History or current   | 1          | I=2*<br>C=3* | I=2*<br>C-3* | I=3*<br>C=3* | I=2* C=3* (See POPs consult notes) | 4   | Phone Consult Any current disease/event within the past year, POPs preferred with Written Consult up to 3 month supply. | Hypoestrogenic effects and reduced HDL with DMPA, Implant, and LNG-IUD. Lipid effects may persist after discontinuation of these methods. There are little effects of reduced HDL with POPs. |

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|--------------------------------------|------------|-------------|--------------|------|--------------|-----|-----------------------|--|
| Stroke                               |            |             |              |      |              |     |                       |  |
| History of cerebrovascular accident√ | 1          | 2*          | I=2*<br>C=3* | 3*   | I=2*<br>C=3* | 4   | Phone Consult         | Hypoestrogenic effects and reduced HDL with DMPA, Implant, and LNG-IUD. Lipid effects may persist after discontinuation of these methods. There are little effects of reduced HDL with POPs.   |
| Valvular heart<br>disease (VHD) √    |            |             |              |      |              |     |                       | Assessment of heart rate is indicated.   |
| Complicated (symptomatic) √          | 1          | 1*          | 1*           | 1*   | 1*           | 4   | Phone Consult         | Complicated diseases in this category include pulmonary HTN, risk for atrial fibrillation, history of subacute bacterial endocarditis. Signs and symptoms may include one or more of the following; chest pain, shortness of breath, exertional symptoms, cyanosis, tachycardia, palpitations. |
| Uncomplicated (asymptomatic) √       | 1          | 1           | 1            | 1    | 1            | 2   |                       | Uncomplicated VHD includes MVP, mitral insufficiency, regurgitation, or murmur that is asymptomatic <b>with no evidence of</b> shortness of breath, cyanosis, and chest pain.  |

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|---|------------|-------------|-------------|------|-----|-------------|---|---|
| Multiple risk factors<br>for atherosclerotic<br>cardiovascular<br>disease   |            |             |             |      |     |             |   |   |
| E.g., age, DM,<br>smoking, HTN, low<br>HDL, high LDL,<br>high triglycerides | 1          | 2           | 2√          | 3√   | 2√  | I=3<br>C=4√ | Consult recommendations in Appendix B.                                  | When a woman has multiple major risk factors, any which will substantially increase her risk for cardiovascular disease; the use of CHCs might increase her risk to an unacceptable level. See Appendix B: Recommendations based on Multiple Risk Factors |
| Cervical cancer Awaiting treatment  | I=4<br>C=2 | I=4<br>C=2  | 2*          | 2*   | 1*  | 2*          | <b>Phone Consult</b>  |   |
| Cervical intraepithelial neoplasia  | 1          | 2           | 2           | 2    | 1   | 2           |   |   |
| Cystic fibrosis   | 1*         | 1*          | 1*          | 2*   | 1*  | 1*          | Phone Consult<br>(immune-<br>compromised<br>state and<br>comorbidities) |   |

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| Deep venous<br>thrombosis (DVT)/<br>pulmonary embolism<br>(PE) |            |             |             |      |     |     |                          |  |
| History of DVT/PE, not receiving anticoagulant therapy√        | 1          | 2           | 2*          | 2    | 2   | 4   | Phone Consult            | <ul> <li>Higher risk is one or more of the following:</li> <li>History of or recurrent DVT/PE</li> <li>Pregnancy associated DVT/PE, Idiopathic DVT/PE, Estrogen associated DVT/PE</li> <li>Known thrombophilia, including antiphospholipid syndrome.</li> <li>Active cancer (metastatic, receiving therapy, or within 6 months after clinical remission), excluding non-melanoma skin cancer.</li> <li>Implant not a method option.</li> </ul> |
| Acute DVT/PE   | 2          | 2           | 2*√         | 2*   | 2*  |     | Phone Consult            | Implant not an ideal method option. Etonogestrel associated of DVT/PE, MI, and CVA.  |
| DVT/PE established anticoagulant therapy for 3 month           | 2          | 2           | 2*√         | 2*   | 2*  | 4   | Phone Consult            | Higher risk as noted above. Implant not an ideal method option.  |
| Family history (first degree relative DVT/PE)                  | 1          | 1           | 1           | 1    | 1   | 2   |                          |  |
| Major surgery with prolonged immobilization                    | 1          | 2           | 2*√         | 2    | 2   | 4   | Phone Consult            | Implant not an ideal method option.  |
| Minor surgery without immobilization                           | 1          | 1           | 1           | 1    | 1   | 1   |                          |  |

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| Depressive disorders                       | 1           | 1√          | 1√          | 1√   | 1√  | 1√  |   | Refer patients if depression is a new finding. Immediate referral and follow-up if any suicidal tendencies are identified.  Reassess mental status with each visit. Counsel the patient each visit regarding risks of recurrent/worsening depression and to contact health department if this occurs. Counsel patient to appraise medical home of contraceptive method. |
| Diabetes                                   |             |             |             |      |     |     |   |   |
| History of gestational diabetes            | 1           | 1           | 1           | 1    | 1   | 1   |   |   |
| Uncomplicated diabetes                     | 1           | 2           | 2           | 2    | 2√  | 2*√ | Written Consult to initiate and annually. | CHC 3 month supply.  If under PMD care, POPs up to 6 month supply.  |
| Complicated diabetes or ≥10 years duration | 1           | 2*          | 2*          | 3*   | 2*√ |     | Written Consult to initiate and annually. | POPs 3 month supply.  If under PMD care, POPs up to 6 month supply.   |
| <b>Dysmenorrhea</b> Severe                 | 2           | 1           | 1           | 1    | 1   | 1   |   |   |
| Endometrial cancer                         | I=4<br>C=2* | I=4<br>C=2* | 1*          | 1*   | 1*  | 1*  | <b>Phone Consult</b>                      |   |
| Endometriosis                              | 2           | 1           | 1           | 1    | 1√  | 1√  |   | CHC, POPs up to 1 year supply. Appendix E:<br>Indications for Extended Use of Hormonal<br>Method  |

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| Epilepsy/Seizures  |            |             |             |      |     |     |                          |  |
| Without<br>anticonvulsant<br>therapy                       | 1          | 1           | 1           | 1    | 1√  | 1√  |                          | CHC, POPs up to 6 month supply. DMPA preferred method.   |
| With anticonvulsant therapy                                | 1          | 1           | 2√          | 1√   | 3*√ | 3*√ | Phone Consult            | See Appendix C: Seizures/Anticonvulsant Therapy Drug Interaction – phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine. Certain anticonvulsants lower effectiveness of methods. DMPA recommended. |
| Gestational trophoblastic disease                          | *          | *           | *           | *    | *   | *   | Phone Consult            |  |
| Headaches√   |            |             |             |      |     |     |                          | Accurate diagnosis of headaches versus migraines and aura is needed.   |
| Non-migraine   | 1          | 1           | 1           | 1    | 1   | 1   |                          |  |
| Migraine without<br>aura (includes<br>menstrual migraine.) | 1          | 1           | 1           | 1    | 1√  | 2√  |                          | POPs 6 month supply For multiple risks factors: see Appendix B. COC use threefold increased risk for ischemic stroke.  |
| Migraine with aura   | 1          | 1*          | 1*          | 1*   | 1*  | 4√  | Written Consult          | COC use threefold increased risk for ischemic stroke.  |

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|---|------------|-------------|-------------|------|-----|---------------------------------|----------------------------------|--|
| History of bariatric surgery              |            |             |             |      |     |                                 |                                  |  |
| Restrictive procedures                    | 1          | 1           | 1           | 1    | 1   | 1                               |                                  |  |
| Malabsorptive procedures                  | 1          | 1           | 1           | 1    | 3*√ | COC:<br>3*√<br>Patch/<br>Ring:1 | Written Consult                  | Pills not preferred secondary to absorption issue.  Must use back up method with COC and POPs.  If dual restrictive and malabsorptive procedure, apply malabsorptive categories. |
| HIV                                       |            |             |             |      |     |                                 |                                  |  |
| High risk for HIV not currently dignosed  | I=2<br>C=2 | I=2<br>C=2  | 1           | 1    | 1   | 1                               |                                  | See Appendix F: Antiretroviral Therapy List  |
| Clinically well receiving ARV therapy     | I=1<br>C=1 | I=1<br>C=1  | *√          | *√   | *√  | *√                              | Phone Consult if patient on ARV. | If on treatment, see Drug Interactions.  |
| Not clinically well receiving ARV therapy | I=2<br>C=1 | I=2<br>C=1  | *√          | *√   | *√  | *√                              | Phone Consult if patient on ARV. | If on treatment, see Drug Interactions.  |

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|--|------------|-------------|-------------|------|-----|--------------|--|--|
| Hypertension√  |            |             |             |      |     |              |  | See HTN in abnormal findings.  |
| Controlled<br>BP < 140/90  | 1          | 1           | 1           | 2    | 1√  | 3*           | Written Consult                            | If under care of PMD and HTN controlled.  POPs 6 month supply.   |
| Stage 1<br>BP>140/90-159/99  | 1          | 1           | 1           | 2    | 1√  |              |  | Referral indicated. <b>Dispensing 3 month supply for POPs.</b>   |
| Stage 2<br>BP\geq 160/100  | 1          | 2           | 2*√         | 3*   | 2*√ | 4            | Written Consult Phone Consult with implant | Implant insertions and/or removal with HTN (consult for guidance.) Referral indicated.  Dispensing 3 month supply for POPs.  |
| Alert BP ≥180/110  | 1√         | 2*√         | 2*√         | 3*√  | 2*√ | 4√           | <b>Phone Consult</b>                       | Same day referral to ER/PMD.  Alert BP dispensing 3 month supply.  |
| Gestation-HTN  | 1          | 1           | 1           | 1    | 1   | 2            |  |  |
| Inflammatory bowel disease (ulcerative colitis or Crohn's disease) | 1          | 1           | 1           | 2*   | 2*  | I=2*<br>C=3* | Phone Consult                              | Patient with post surgery for IBD may have malabsorption and oral methods should be avoided.  Women who have extensive disease, surgery, immobilization, steroid use, vitamin and fluid depletion are at increased risk for VTE, consult as indicated. |
| Known<br>thrombogenic<br>mutations                                 | 1          | 2           | 2*√         | 2    | 2   | 4            | Phone Consult Implant not a method option. | Etonogestrel has been associated with an increased risk of DVT/PE, MI and CVA. POPs 3 month supply.  |

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|-------------------------------------|------------|-------------|-------------|------|-----|-----|--------------------------|---|
| Liver tumors                        |            |             |             |      |     |     |                          |   |
| Benign focal nodular hyperplasia    | 1          | 2*          | 2*          | 2*   | 2*  | 2*  | <b>Phone Consult</b>     |   |
| Benign<br>hepatocellular<br>adenoma | 1          | 3*          | 3*          | 3*   | 3*  | 4   | Phone Consult            |   |
| Malignant (hepatoma)                | 1          | 3*          | 3*          | 3*   | 3*  | 4   | <b>Phone Consult</b>     |   |
| Gallbladder disease                 |            |             |             |      |     |     |                          |   |
| Symptomatic                         |            |             |             |      |     |     |                          |   |
| Treated by cholecystectomy          | 1          | 2           | 2           | 2    | 2   | 2   |                          |   |
| Medically treated                   | 1          | 2           | 2           | 2    | 2   | 3*√ | <b>Phone Consult</b>     | CHC may worsen gallbladder disease.   |
| Current                             | 1          | 2           | 2           | 2    | 2   | 3*  | <b>Phone Consult</b>     |   |
| Asymptomatic                        | 1          | 2           | 2           | 2    | 2   | 2   |                          |   |
| Hepatitis (Viral)                   |            |             |             |      |     |     |                          |   |
| Acute or symptomatic liver disease  |            |             |             |      |     |     | Phone Consult            | Discontinue method, obtain LFTs and refer. Acute s/sx: jaundice, sclera icterus, abdominal varicosities, ascites, and enlarged liver. |
| Carrier/Chronic                     | 1          | 1           | 1           | 1    | 1√  | 1√  |                          | If patient is asymptomatic, LFTs are not required. May initiate up to a 6 month supply.   |

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| 1 RISK FACTOR                | Cu-<br>IUD | LNG-<br>IUD | Im<br>plant | DMPA | POP | СНС                             | CONSULT<br>(* = Consult)                            | COMMENTS $(\sqrt{=\text{Comments}})$   |
|------------------------------|------------|-------------|-------------|------|-----|---------------------------------|---|--|
| Multiple sclerosis           |            |             |             |      |     |                                 |   |  |
| With prolonged immobility    | 1          | 1           | 1           | 2√   | 1   | 3*                              | Phone Consult                                       | Women with MS might have compromised bone health from disease related disability, immobility, and use of corticosteroids.  |
| Without prolonged immobility | 1          | 1           | 1           | 2√   | 1   | 1                               |   | Women with MS might have compromised bone health from disease related disability, immobility, and use of corticosteroids.  |
| Obesity                      |            |             |             |      |     |                                 |   |  |
| BMI≥30                       | 1          | 1           | 1           | 1    | 1√  | 2*√ (See consult BMI exception) | BMI≥35, Phone Consult required for combined method. | POPs 6 month supply. Obese women (BMI ≥35) who use CHC have increased risk of VTE.   |
| Menarche <18 yr. & BMI>30    | 1          | 1           | 1           | 2    | 1√  | 2*√                             | Phone Consult                                       | POPs 6 month supply.  Obese women who use CHC are 2-3 times higher risk for VTE than normal weight women regardless of COC use.  Effectiveness of the patch might be reduced in women >90kg. |
| Postabortion $\sqrt{}$       |            |             |             |      |     |                                 |   | See Appendix G: How to be Reasonably<br>Certain that a Women is Not Pregnant   |
| First Trimester              | 1          | 1           | 1           | 1    | 1   | 1                               |   |  |
| Second Trimester             | 2          | 2           | 1           | 1    | 1   | 1                               |   |  |
| Immed. Postseptic            | 4          | 4           | 1           | 1    | 1   | 1                               |   |  |

**DISCLAIMER:** Guidelines based on 1 Risk Factor. A consult is required for categories with an asterisk (\*). A consult is also required for patients currently diagnosed with cancer or cancer within the last 5 years. Dispensing Categories: 1 = 12 month supply, 2 = 6 month supply, 3 = 3 month supply, initial patients = 3 month supply unless established on a method. Consult annually after initial consult unless issue is resolved.

| 1 RISK FACTOR                                    | Cu-<br>IUD  | LNG-<br>IUD | Im<br>plant | DMPA          | POP | СНС | CONSULT<br>(* = Consult)      | COMMENTS $(\sqrt{=\text{Comments}})$                                |
|--|-------------|-------------|-------------|---------------|-----|-----|-------------------------------|---|
| Rheumatoid arthritis                             |             |             |             |               |     |     |                               |   |
| On immunosuppressive therapy                     | I=2<br>C=1  | I=2<br>C=1  | 1           | I=2*√<br>C=3* | 1√  | 2*  | Written Consult               | DMPA not ideal if steroid use ≥6 months. POPs 6 month supply.       |
| Not on immunosuppressive therapy                 | 1           | 1           | 1           | 2             | 1√  | 2   |                               | DMPA not ideal if steroid use $\geq$ 6 months. POPs 6 month supply. |
| Superficial venous disorders                     |             |             |             |               |     |     |                               |   |
| Superficial venous thrombosis (acute or history) | 1           | 1           | 1           | 1             | 1   | 3   | Phone Consult if complicated. |   |
| Systemic lupus erythematosus                     |             |             |             |               |     |     |                               |   |
| Positive or unknown anti-phospholipid antibodies | 1           | 3*          | 3*          | 3*√           | 3*  | 4   | <b>Phone Consult</b>          | DMPA not an ideal choice if patient on steroids >6 months.          |
| Severe thrombo-<br>cytopenia                     | I=3*<br>C=2 | 2           | 2*          | I=3*√<br>C=2  | 2   | 2   | Phone Consult                 | DMPA not an ideal choice if patient on steroids $\geq$ 6 months.    |
| Immunosuppressive therapy                        | I=2<br>C=1  | 2           | 2*          | I=2√<br>C=2   | 2   | 2   | Phone Consult                 | DMPA not an ideal choice if patient on steroids ≥6 months.          |
| None of the above                                | I=1<br>C=1  | 2           | 2*          | I=2√<br>C=2   | 2   | 2   | <b>Phone Consult</b>          | DMPA not an ideal choice if patient on steroids ≥6 months.          |

**DISCLAIMER:** Guidelines based on 1 Risk Factor. A consult is required for categories with an asterisk (\*). A consult is also required for patients currently diagnosed with cancer or cancer within the last 5 years. Dispensing Categories: 1 = 12 month supply, 2 = 6 month supply, 3 = 3 month supply, initial patients = 3 month supply unless established on a method. Consult annually after initial consult unless issue is resolved.

| 1 RISK FACTOR                                  | Cu-<br>IUD | LNG-<br>IUD | Im<br>plant | DMPA | POP | СНС | CONSULT<br>(* = Consult)  | COMMENTS $(\sqrt{=\text{Comments}})$  |
|--|------------|-------------|-------------|------|-----|-----|---|---|
| Thyroid disorders                              |            |             |             |      |     |     |   |   |
| Simple goiter/<br>hyperthyroid/<br>hypothyroid | 1          | 1           | 1           | 1    | 1√  | 1√  | Written Consult Assess for severity or symptomatic Hyper/Hypo Thyroidism. (See comments.) | If symptomatic and not under the care of PMD, obtain thyroid profile, if results abnormal, phone consult and refer.  If followed by outside provider, no lab needed.  If thyroid storm symptomology, phone consult and refer.  For dispensing – 6 month supply okay when under care of physician. If asymptomatic and not under care of physician obtain thyroid profile, dispensing – 3 months, if results are abnormal consult and refer. |
| Thyroid cancer                                 | *          | *           | *           | *    | *   | *   | <b>Phone Consult</b>  |   |

# **Appendix A: Low Risk Patients with Breast Masses**

- Age < 25 years old
- No first degree relative with history of breast cancer
- Correlation of dietary habits and breast masses (i.e., excessive caffeine intake)
- Correlation of hormones/menses to breast lesions
- Correlation of bilateral cyclic breast pain
- Correlation of fibrocystic changes in breast abnormalities (see protocol Abnormal Findings Chapter-Breast Abnormalities)
- May initiate a method while expedited evaluation pending
- All palpable masses require immediate surgical evaluation with diagnostic work-up and abnormal breast follow-up to collaborating physician as with any palpable breast mass in any age (see protocol-Abnormal Findings and Follow-Up Chapters).
- Consult collaborating physician with any variation of young and low risk patients for breast cancer regarding birth control management.

**Appendix B: Recommendations based on Multiple Risk Factors** 

|  | Combined   | Progestin-only  |
|--|--|---|
| <ol> <li>Age ≥ 35 years old</li> <li>Smoker</li> <li>Overweight (BMI 27-29)</li> <li>Obese (BMI ≥ 30)</li> <li>Hypertension</li> <li>Diabetes</li> <li>Migraines</li> </ol>                                      | NO COMBINED METHODS  See exceptions below  | <ul> <li>Any progestin-only method is acceptable unless specified in "Exceptions" section below.</li> <li>No consult required for NP. See "Exceptions" below for nurses. May provide up to 3 month supply.</li> </ul>     |
|  | EXCEPTIONS   |   |
| <ul> <li>If any combination of:</li> <li>Uncontrolled         Hypertension consisting         of ≥160/≥100;</li> <li>Diabetes (vascular or ≥         10 years duration);</li> <li>Migraines with Aura</li> </ul> | NO COMBINED METHODS  | <ul> <li>Phone consult is required for Implant, otherwise written consult is indicated to initiate and annually. May initiate or continue any progestin-only method</li> <li>May provide up to 3 month supply.</li> </ul> |
| Overweight (BMI 27-29)<br>Migraines (without aura)<br>< 35 years   | <ul> <li>COCs and rings: acceptable method.</li> <li>*Patch: dispense with caution.</li> <li>**Utilize discretion to issue up to a 6 month supply except with patch (3 month supply).</li> <li>NP No consult required for NP.</li> </ul>   | <ul> <li>Any progestin-only method is acceptable.</li> <li>No consult required for nurse or NP.</li> <li>May provide up to 6 month supply.</li> </ul>   |
| Overweight (BMI 27-29) Controlled Hypertension < 35 years  Overweight (BMI 27-29) Non-vascular Diabetes < 35 years   | <ul> <li>COCs and rings: acceptable method.</li> <li>*Patch: dispense with caution.</li> <li>NPWritten consult required to initiate and annually while on combined method.</li> <li>Closer monitoring required; 3 month supply.</li> </ul>   | NOTE: The standard overweight BMI range is 25-29, although for the purposes of this protocol, the BMI range of 25-26 is <u>not</u> considered a risk factor.  |
| Overweight (BMI 27-29)  > 35 years   | Phone consult required to initiate and annually while on combined method.  |   |
| Obese BMI > 30 and<br>≥35 years  | NO COMBINED METHODS  |   |
| Overweight (BMI 27-29)<br>Smoker<br>< 35 years   | <ul> <li>COCs and rings: acceptable method.</li> <li>*Patch: dispense with caution.</li> <li>**Utilize discretion to issue up to a 6 month supply</li> <li>No consult required for nurse or NP.</li> </ul>   |   |
| Obese Smoker<br>< 35 years   | <ul> <li>BMI 30-34:</li> <li>COCs and rings: acceptable method.</li> <li>*Patch: dispense with caution.</li> <li>**Utilize discretion to issue up to a 6 month supply except with patch (3 month supply).</li> <li>No consult required for nurse or NP.</li> <li>BMI &gt; 35: NO COMBINED METHODS</li> </ul> |   |

# **Appendix C: Seizures/Anticonvulsant Therapy**

|          | Combined  | Progestin-only   |
|----------|---|--|
| Seizures | <ul> <li>COCs and rings: acceptable method.</li> <li>Patch: dispense with caution.</li> <li>Utilize discretion to issue up to a 6 month supply except with patch (3 month supply).</li> <li>No consult required for nurse or NP Counsel patient to apprise medical home.</li> </ul>   | <ul> <li>Any progestin-only method is acceptable.</li> <li>NOTE: Depo preferred choice for patients on anticonvulsant drugs based on the possibility that it may decrease seizures and effectiveness is not compromised.</li> <li>No consult required for nurse or NP.</li> <li>May provide up to 6 month supply.</li> </ul> |
|          | may alter the efficacy of hormonal contraceptive back-up method maybe needed. If patient's only COCs are not recommended due to their effects medication.  Per ACOG:  Anticonvulsants that induce hepatic enzymes can deprogestin component of combined oral contraceptive condoms in conjunction with the method.  Anticonvulsants that decrease steroid levels in word.  Barbiturates: Phenobarbital Luminal®, Solfoto Phenytoin: Dilantin®, Phenytek®  Carbamazepine: Tegretol®  Carbamazepine: Trileptal®  Felbamate: Felbatol®  Topiramate: Topamax®  Vigabatrin: Sabril®  Lamotrigine: Lamictal®  Anticonvulsants that do not induce hepatic enzyments. | decrease serum concentrations of the estrogen and ves, therefore, patients should be counseled to use men taking hormonalmethods include: on®; Primidone  es Anticonvulsants that donot decrease steroid levels in lude: Ethosuximide (Zarontin®), Gabapentin (brand upentin®), Levetiracetam (Keppra®), Tiagabine           |

# **Appendix D: Polycystic Ovary Syndrome (PCOS)**

|                     | Combined or Progestin-only   |
|---------------------|--|
| <b>O</b> NP<br>PCOS | <ul> <li>NP may initiate or continue a hormonal method if menstrual pattern over the prior<br/>year consists of periods every 3 months. Counsel patient to apprise medical home. No<br/>consult required.</li> </ul>   |
|                     | <ul> <li>Low-androgen OC (such as Ortho Tri-Cyclen or Ortho Cyclen), or<br/>progestin-only methods preferred.</li> </ul>   |
|                     | ■ <b>Phone consult</b> required to initiate or continue hormonal method if amenorrhea occurs for 6 months or longer. Provide pertinent information in consult such as detailed description of menstrual pattern over prior year, pregnancy test results, characteristics of PCOS, etc. |
|                     | <ul> <li>Patient established on Depo-Provera with amenorrhea may continue this method<br/>without consult or referral.</li> </ul>  |

<u>PCOS</u> - The key concern from a GYN standpoint is the possibility of long term/chronic unopposed estrogen, which can create a hyperplastic endometrium (precursor to endometrial cancer). Women with PCOS are often obese and hirsute, but not always.

A menstrual history compatible with PCOS warrants referral for evaluation and consideration of an endometrial assessment <u>prior to</u> initiating hormonal methods. This includes not only secondary amenorrhea but also a pattern of irregular bleeding (variable timing and volume/duration).

Bleeding in the latter might represent crumbling of the superficial layers of a hyperplastic endometrium rather than true cyclic menstrual shedding. Long standing chronic anovulation is the main concern and warrants medicalmanagement.

<u>Metabolic Syndrome</u> - Metabolic syndrome is a cluster of conditions (increased blood pressure, elevated insulin levels, excess body fat around the waist or abnormal cholesterol levels) that occur together, increasing the risk of heart disease, stroke and diabetes. This condition is associated with insulin resistance. Researchers are still learning what causes insulin resistance.

It probably involves a variety of genetic and environmental factors. Some people may be genetically prone to insulin resistance, inheriting the tendency from their parents. Being overweight and inactive are major contributors.

Due to its link to obesity and insulin resistance, women with PCOS are at an increased risk for this cluster of conditions. Counsel patient that she needs a medical home for work-up and ongoing management.

# **Appendix E: Indications for the Extended Use of Hormonal Methods**

- Extended use is defined as bicycling (active pills or rings for six weeks), tricycling (Active pills or rings for 9 weeks), or name brands Seasonale/Seasonique for (12 weeks).
- Nuvarings or Combine Oral Contraceptives may be used.
- Indicated for medical or personal preference to have fewer bleeding days.
- Indicated for Dysmenorrhea, Endometriosis, and stable Uterine Fibroids.
- Indicated for military workers, women working long hours, athletes, honeymoons, trips, and vacations and those who find menses inconvenient.
- May be beneficial to menstrual migraines and other cyclic headaches
- May be beneficial to cyclic symptoms associated with arthritis, asthma, and polycystic ovarian disease.

# **Appendix F: Antiretroviral Therapy**

- A. Nucleoside reverse transcriptase inhibitors (NRTIs)
  - Abacavir (ABC)
  - Tenofavir (TDF)
  - Zidovudine (AZT)
  - Lami vudine (3CT)
  - Didanosine (DDI)
  - Erntricitabine (FTC)
  - Stavudine (D4T)
- B. Non-Nucleoside reverse transcriptase inhibitors (NNRTIs)
  - Efavirenz (EFV)
  - Etravirine (ETR)
  - Nevarapine (NVP)
  - Rilpivirine (RPV)
- C. Ritonavir-boosted protease inhibitors (PIs)
  - Ritonavir-boosted atazanavir (ATV/r)
  - Ritonavir-bosted darunavir (DRV/r)
  - Ritonavir-boosted fosernprenavir (FPV/r)
  - Ritonavir-boosted lopinavir (LPV/r)
  - Ritonavir-boosted saquinqvir (SQV/r)
  - Ritonavir-boosted tipranavir (TPV/r)
- D. Protease inhibitors without ritonavir
  - Atazanavir (ATV)
  - Fosamprenavir (FPV)
  - Indinavir (IDV)
  - Nelfinavir (NFV)
  - CCR5 C0-receptor antagonists
- E. HIV Integrase strand transfer inhibitors
  - Raltegravir (RAL)
  - Dolutegravir (DTG)
  - Elvitegravir (EVG)
- F. Fusion inhibitors
  - Enfuvirtide

# Appendix G: How to be Reasonably Certain that a Woman is Not Pregnant

A health care provider can be reasonably certain that a woman is not pregnant if she has no symptoms or signs of pregnancy and meets one of the following criteria:

- <7 days after the start of normal menses
- has not had sexual intercourse since the start of last normal menses
- has been correctly and consistently using a reliable method of contraception
- ≤7 days after spontaneous or induced abortion
- within 4 weeks postpartum
- fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [>85%] of feeds are breastfeeds), amenorrheic, and <6 months postpartum

On the basis of clinical judgment, health care providers might consider the addition of a urine pregnancy test; however, they should be aware of the limitations, including accuracy of the test relative to the time of last sexual intercourse, recent delivery, or spontaneous or induced abortion. Routine pregnancy testing for every woman is not necessary. If a woman has had recent, within the last 5 days, unprotected sexual intercourse, consider offering emergency contraception if pregnancy is not desired.

If  $\leq$ 7 days after spontaneous or induced abortion, may initiate method with 2 weeks follow up urine HCG.

Centers for Disease Control and Prevention (2016). U.S. Selected Practice Recommendations for Contraceptive Use, 2016.

# **Appendix H: Identifying Migraine Headaches Tools/Forms**

It is important to identify women who have a history of migraine headaches due to the increased risk of stroke, particularly if accompanied by aura. A thorough history and physical is necessary to evaluate headache complaints. It is important to understand the specific characteristics of the headaches in order to determine if it is in fact, a migraine. Characteristics to assess include: onset, location, frequency, duration, exacerbating and alleviating factors, and symptoms.

#### **Definitions**

- 1. <u>Migraine without aura</u> The common migraine is a disorder involving recurrent headaches, which may be accompanied by a broader set of changes that can occur throughout the body such as nausea, vomiting, sensitivity to light, etc.
  - a. <u>Prodromal phase</u> The prodromal phase of a migraine includes the early sensations a migraineur can have preceding the attack. Typically these early sensations might include a change in mood, appetite, or activity level and it is an indication that the migraine is coming.
- 2. <u>Migraine with Aura</u> Some people also experience visual and sensory disturbances shortly before the headache begins, which is known as aura. Such disturbances generally last anywhere from 10-30 minutes and in some cases; do not result in a headache. Auras may change in frequency or type over a person's lifetime.

Questions to ask when determining the type of headache. The table below describes questions that can be asked when completing the health history to determine the characteristics of a patient's headaches.

When did you start having headaches?

How often do they occur?

How long do they last?

Are they associated with your menstrual cycle?

Does anything seem to trigger them?

Do you have other symptoms with the headache?

Do you notice any visual problems before or after your headaches?

# **Appendix H: Identifying Migraine Headaches Tools/Forms** (Continued)

## Onset, duration and frequency of migraines

| Onset     | Headaches may begin at any time of the day or night; and while a sufferer may wake up with one, a migraine will rarely awaken a person from sleep. As described above, those who experience aura generally have disturbances from 10-30 minutes before the actual onset of the headache. |
|-----------|--|
| Frequency | Most migraine sufferers experience two to four headaches per month; some get one every few days, and others may only have one or two a year.   |
| Duration  | Most migraine headaches last at least four hours, although very severe ones can last up to a week.   |

**Precipitating Factors**. The following is a list of precipitating factors that can be associated with triggering a migraine:

<u>Physical and emotional causes</u> - Stress, Fatigue, oversleeping or lack of sleep, menses, hormonal changes, changes in barometric pressure, physical activity, loud noises, bright lights (including sun glare), strong odors (including smoke) and changes in altitude.

#### Food and Diet

Fasting or missing a meal, caffeine, chocolate, alcohol (red wines), yellow (annatto) food coloring, and MSG (monosodium glutamate) - canned or processed foods, Chinese foods, tenderizer, and seasonings such as soy sauce may contain MSG; aged cheeses; processed meats (including pizza and hot dogs); peanuts; chicken livers; pickled foods; sourdough bread; bread and crackers containing cheese; broad beans, peas, lentils.

Typical foods to eat in moderation include: avocados, bananas, citrus fruits, figs, raisins, red plums, raspberries, and chocolates.

# **Appendix H: Identifying Migraine Headaches Tool/Forms** (Continued)

# Signs/Symptoms

| Migraines without Aura                                | Migraines with Aura   |
|---|---|
| Nausea  | Unilateral numbness   |
| Vomiting  | A "pins-and-needles" sensation  |
| Photophobia - sensitivity to light; flickering lights | Unilateral weakness   |
| Phonophobia - sensitivity to sound                    | Visual disturbances in one or both eyes - zig zag lines that gradually float across the field of vision (scintillations); temporary blindness or blind spots (scotomas) |
| Visual blurring; generalized spots/flashing           | Tingling on one side of the body, often in the hand, arm or face; partial paralysis   |
| Movement makes the pain worse                         | Difficulty in speaking  |
|   | Olfactory hallucinations (smelling odors that are not really there)   |