C5.8 - COMBINED ORAL CONTRACEPTIVE PILLS

Policy

This policy outlines the use of combined oral contraceptive pills, containing estrogen and progestin to prevent pregnancy.

Procedure

Mode of Action

The primary mechanism of action is hormonal inhibition of ovulation by suppressing the release of gonadotropins. Also, progesterone alters cervical mucous inhibiting sperm motility into the uterus.

Effectiveness

Theoretical effectiveness rate is 99.7%.
Typical use effectiveness rate is 91%.

Contraindications

Absolute Contraindications

- Thrombophlebitis, thromboembolic disorders, cerebral vascular disease, coronary occlusion, or a past history of these conditions
- Acute/current DVT and/or PE.
- Any history of VTE (venous thromboembolism) including DVT or PE with higher risk of recurrence.
- Major surgery planned with prolonged immobilization
- Markedly impaired liver function (steroid hormones are contraindicated in patients with acute viral hepatitis or during a flare) such a severe cirrhosis.
- Known or suspected breast cancer.
- Undiagnosed abnormal vaginal bleeding.
- Known or suspected pregnancy.
- Smokers over the age of 35 who smoke more than 15 cigarettes daily (see CDC US Medical Eligibility Criteria).
- Complicated solid organ transplantation
- Poorly controlled hypertension (systolic ≥140 or diastolic ≥90 or as indicated by The American Heart Associations most recent guidelines)
- Migraines headaches **with** aura
- Diabetes with complications i.e., nephropathy, retinopathy, neuropathy, other vascular disease or diabetes >20 years duration.
- Known or suspected carcinoma of the endometrium or other estrogen-dependent cancer.
- Liver cancer or hepatocellular adenoma.
- Peripartum cardiomyopathy with moderately or severely impaired cardiac function.
- Within 6 months of peripartum cardiomyopathy with normal or impaired cardiac function.
- Less than 21 days postpartum in both breastfeeding and non-breastfeeding clients.

Strong Relative Contraindications

- Gallbladder disease that is being medically managed or is currently active/symptomatic.
- Previous cholestasis on combined hormonal contraceptives.
- Well controlled hypertension with resting BPs Systolic reading of 130-139 and Diastolic reading between reading of 80-89 on three different occasions (or as indicated by The American Heart Associations most recent guidelines)
- Chronic renal disease with hypertension.
- Clients over 35 who smoke less than 15 cigarettes/day (see CDC US MEC Criteria).
- History of a malabsorptive procedure type of bariatric surgery (this includes Roux-en-Y), however restrictive procedures are not a contraindication. Other administration methods for estrogen containing contraception (such as the ring or patch) is acceptable for mal-absorptive procedures.
- See specific drug interaction information for antiretroviral, anticonvulsants and antimicrobial (specifically rifampin or rifabutin) medication.
- More than six months after peripartum cardiomyopathy with normal or impaired cardiac function.
- Clients 21-30 days postpartum with other risk factors for VTE (age >35, history of VTE, BMI >30, smoking and others).
- Breastfeeding clients up to 30 days postpartum with or without other risk factors for VTE.
- Breastfeeding clients 30-42 days postpartum with other risk factors for VTE.

Relative Contraindications

Refer to the Appendix for the CDC Medical Eligibility Criteria Summary Chart

Combined Oral Contraceptives for Women in Later Years

- Clients aged 35 and older may continue to use oral contraceptives in the absence of risk factors.
- Clients who have current or past history of thrombophlebitis or thromboembolic disorder, or cardiovascular disease, diabetes with vascular involvement, smoke more than 15 cigarettes daily, or are hypertensive, should not use combined oral contraceptives. The risks to clients with hyperlipidemia who use combined oral contraceptives usually outweigh the advantages.

Advantages

- Reliable method of contraception when used properly.
- There is no interference with the normal sequence of sexual relations.
- There are no requirements for preparation or disposal.
- Patient controls starting and stopping the method

Definitely Beneficial

- Improved uterine bleeding (lighter and more predictable).
- Decreased dysmenorrhea.
- Decreased ovulatory symptoms (i.e. Mittelschmerz).
- Suppression of endometriosis.
- Improved acne and hirsutism.
- Prevention of menstrual porphyria.

Probably Beneficial

- Prevention of functional ovarian cysts.
- Decrease in premenstrual symptoms.
- Control of bleeding (dyscrasia, anovulation).

Noncontraceptive Benefits

- Decreased endometrial cancer.
- Decreased ovarian cancer.
- Decreased benign breast disease.
- Fewer ovarian cysts.
- Fewer uterine fibroids.
- Fewer ectopic pregnancies.
- More regular menses, decreased menstrual flow, decreased dysmenorrhea, decreased anemia.
- Decreased salpingitis.
- Decreased incidence of sickle cell crisis

Disadvantages

- Increased risk of venous thromboembolism (VTE).
- Must remember to take pill every day at the same time.
- Does not protect against STIs.
- Possible decreased libido.

Side Effects

- Nausea, typically resolves.
- Fluid retention, breast fullness, or tenderness.
- Breakthrough bleeding (common in first three months of use).
- Decreased menstrual flow (not always a nuisance).
- Missed periods.
- Melasma.
- Libido alterations.
- Interaction with other drugs.
- If history of epilepsy, diabetes, hyperlipidemia, liver impairment, client should inform Clinical Services Provider if hormonal contraception is planned.
- Use of certain anticonvulsants can alter the effectiveness of oral contraceptives. These include, but is not limited to the following: phenytoin, carbamazepine, barbiturates, lamotrigine, primidon topiramate, and oxcarbazepine.

Possible Complications

Possible Life-Threatening

- Venous thromboembolism: blood clots in the legs, pelvis, lungs or brain (see Initial Pill Selection).
- Liver tumors (hepatocellular adenomas).

Serious, but rare

- Gallbladder disease.
- Hypertension.

Warning Signs

- Call the clinic or report to the ER if any of the following warning signs should occur:
  - **A**..... Abdominal Pain (severe)
  - **C**..... Chest Pain (shortness of breath)
  - **H**..... Headaches (severe)
  - **E**..... Eye Problems (blurred or loss of vision)
  - **S**..... Severe Leg Pain (calf or thigh)

Lactation Concerns and the Combination Pill

- Mini-pill (progestin only) is preferred for clients immediately after delivery due to the increased risk of VTE in the immediate postpartum period.
- A combination oral contraceptive pill may be prescribed after 1 month postpartum (U.S. Medical Eligibility Criteria), under the following conditions:
  - Shared decision-making about the risk of unplanned, short interval pregnancy, and theoretical risk of decreases in lactation with initiation of combined hormonal contraception.
  - Client understands that small amounts of hormone may be present in breast milk, and that this is safe for baby.
- Breastfeeding clients who do not have additional VTE risk factors may reasonably begin combination oral contraception at 30 days postpartum. However, breastfeeding clients with additional VTE risk factors should delay CHC initiation until at least 42 days (six weeks) postpartum. Please refer to CDC MEC for additional guidance: https://www.sciencedirect.com/science/article/abs/pii/S0010782415004825

Instructions to the client

Instruct client that oral contraceptive pills do not protect against acquiring STIs/HIV. A barrier contraceptive should be used in combination with pills to help reduce the risk of STIs.

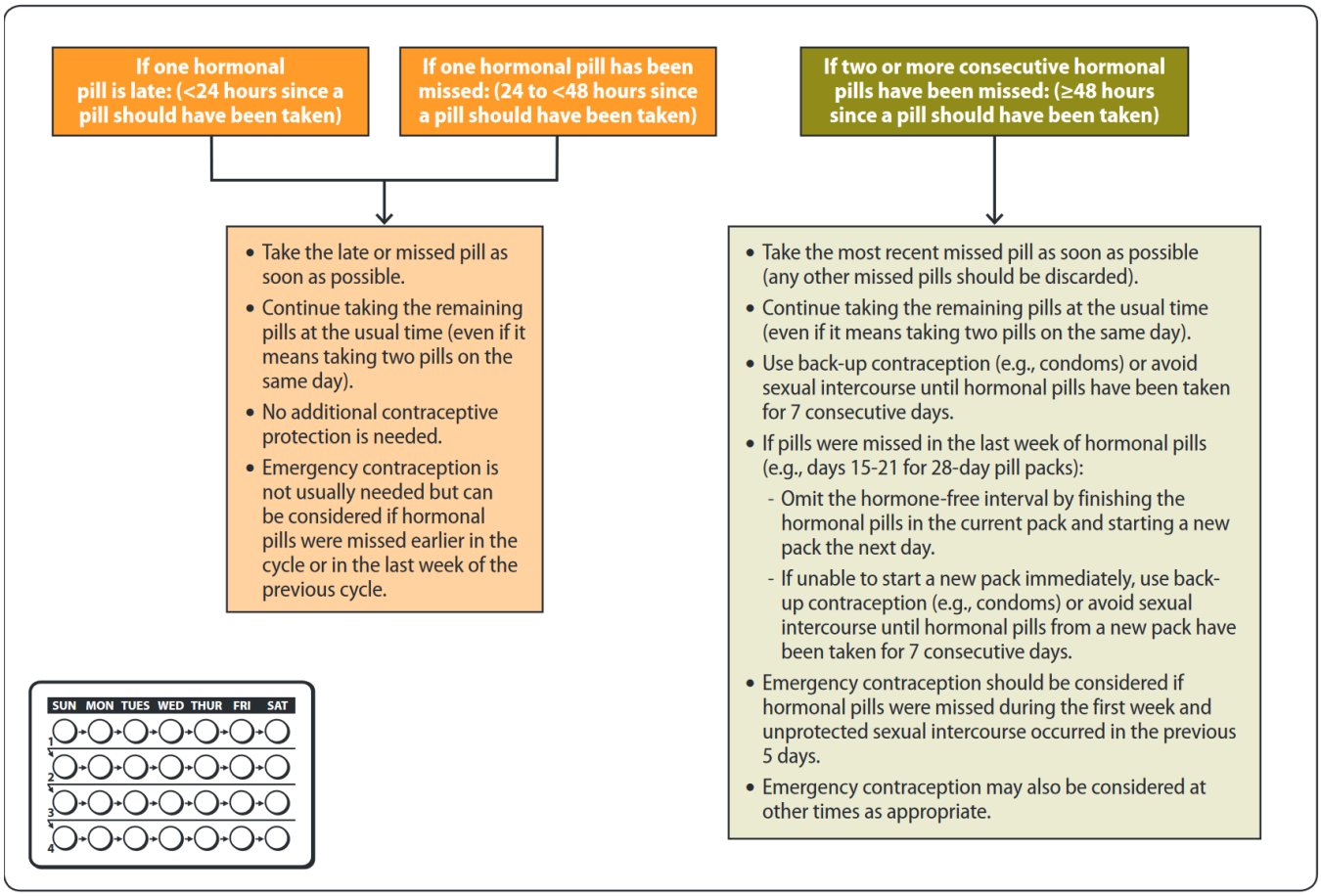
1. When to initiate pills for a new or restart FP client (not postpartum, not post-abortion, and not currently on pills):
   a. Day 1 Start (28 day regimen): One tablet is taken daily from the first day of the menstrual cycle through day 28, counting the first day of the menstrual flow as "Day 1".
   b. Sunday Start (28-day regimen): The first pill is taken on the Sunday after the start of menses. If menses starts on Sunday, the first pill should be taken on that day, and continued throughout the 28 days. With either the same day or Sunday start, the client should be encouraged to use a back-up method of condoms for seven (7) consecutive days.
   c. Quick Start: If there is no suspicion of pregnancy, take the first pill in the clinic. Count the day the first pill is taken as day 1. Counsel that client is not fully protected until pills are taken for seven (7) days. Offer condoms as a back-up method. Document that condoms were offered.
2. Postpartum in a non-breastfeeding client:
   a. Clients 21-42 days postpartum without other risk factors for VTE. Rule out pregnancy and begin pills per normal initiation protocol. Counsel that client is not fully protected until pills have been taken for 7 days.
3. Post-abortion:
   a. Up to 2 weeks if no risk of pregnancy, initiate pills per normal pill initiation protocols. Client is not fully protected until pills are taken for seven (7) days. Offer condoms for a back-up method, document.

b. Initiate pills per normal protocol after menses. Client is not fully protected until pills have been taken for 7 days. Offer condoms, and document.

Making Up Missed Pills (See diagram following)

1. If you MISS one "active" pill:
    a. Take as soon as you remember. Take the next pill at your regular time if it has been less than 24-hours since you missed it. You do not need to use a back-up birth control method.
2. If you missed pills early in the cycle or during the last week of the previous cycle, you may want to use EC. If you MISS two or more "active" pills in a row:
    a. Take the most recent missed pill as soon as possible. This means you will take two pills on the day you remember them. Discard any other missed pills.
    b. Then take 1 pill a day until you finish the pack.
    c. You MAY BECOME PREGNANT if you have sex in the 7 days after you miss pills. You MUST use another birth control method (such as male condoms, female condoms, foam, contraceptive sponge or abstinence) until you have taken the pills correctly for 7 days in a row.
    d. Offer EC. *Reference Emergency Contraception policy.*
    e. If you miss pills in the last week of the hormonal pill, do not take the hormone free pills, simply finish the rest of any hormone pills and then immediately start a new pack. If you are unable to start a new pack right away, use a back-up method of birth control or abstain from intercourse until you can start the new pack and have taken 7 consecutive pills from the new pack.
3. If you forget any of the seven "reminder" pills in Week 4:
    a. THROW AWAY the pills you missed.
    b. Keep taking 1 pill each day until the pack is empty.
    c. You do not need a back-up method.
    d. Make sure to start a new pack no more than 7 days after completing the active pills.
4. Client should call the clinic if one of the following situations should occur:
    a. If one or more pills is missed and no menses occur.
    b. If two (2) consecutive menses are missed (regardless of whether any pills were missed).
    c. If intermenstrual spotting occurs for 3 or more cycles.

Recommended Actions After Late or Missed Combined Oral Contraceptives



Centers for Disease Control and Prevention
National Center for Chronic Disease Prevention and Health Promotion

For the full recommendations, see the US Selected Practice Recommendations for Contraceptive Use, 2013 (http://www.cdc.gov/mmwr/pdf/rr/rr6205.pdf).

Extended Cycle OCP Use

- Up to 91-day cycle or 13 week cycle, 84 days of active pills/7 days of inactive pills with up to four withdrawal bleeds per year.
- It is also an option for continuous use during which the client takes an active pill every day without any pill-free/inactive pill interval.
- Unless prescribing a pill formulation specifically designed for extended cycle use (ie seasonale®), the client will need 15-17 packs per year.
- Additional advantages of extended cycle dosing include overall decreased bleeding, reduction in headaches, premenstrual symptoms and mood changes that occur during the inactive pill period.
- Same mechanism of action as regular combined contraceptive pills and same effectiveness.
- Same contraindications as regular combined contraceptive pills.
- Same advantages and disadvantages as regular combined contraceptive pills with an additional advantage of only four withdrawal bleeds per year instead of 13.
- May allow for improved ovulatory suppression in obese patients.

- Same side effects as combined contraceptive pills with the additional side effect of increased likelihood of break through bleeding during the first few cycles.
- Same instructions as regular combined contraceptive pills except that it is up to a 91 day/ 13 week regimen not 28 day/4 week regimen.

Fertility Return

Return to fertility after discontinuation of oral contraceptive pills is typically rapid (within 4 weeks), although variable, and clients should be encouraged to initiate alternative contraception immediately if they are not desiring pregnancy.

Date Revised	**September 2023**
References	Providing Quality Family Planning Services Recommendations of CDC and the U.S. Office of Population Affairs (QFP) [2014] (https://www.hhs.gov/opa/guidelines/clinical-guidelines/quality-family-planning/index.html)
Additional Resources	Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use, 2020 (https://www.cdc.gov/reproductivehealth/contraception/pdf/summary-chart-us-medical-eligibility-criteria_508tagged.pdf)