**(insert AGENCY name)**

Reproductive Health Program

Clinical Practice Standard

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| **Subject:** Combination Oral Contraceptives | **No.** |
| **Approved by:**  |  | **Effective Date:**  |
| **Revised Date:** March 2017, January 2018, January 2019; January 2021, **October 2022** |
| **References:** U.S. Medical Eligibility Criteria for Contraceptive Use (U.S. MEC), 2016; U.S. Selected Practice Recommendations for Contraceptive Use (U.S. SPR), 2016; Contraceptive Technology, 21st Ed; Providing Quality Family Planning Services (CDC QFP), 2014 |

**POLICY:** This Clinical Practice Standard follows the recommendations of the U.S. MEC, 2016; U.S. SPR, 2016; Contraceptive Technology, 20th Ed., and CDC QFP, 2014.

**PURPOSE:** This Clinical Practice Standard provides direction for reproductive health clinics to assist clients in their use of combined oral contraceptives.

Combined oral contraceptives (COCs) contain both estrogen and a form of progestin. COCs are generally used for 21-24 consecutive days, followed by 4-7 hormone-free days. These methods can also be used for an extended period with infrequent or no hormone-free days. While some COCs are designed and packaged for extended use, extended cycling can be accomplished with a 21/7 combination OCP regimen by omitting the seven placebo pills in the pack and beginning a new pack on day 22. Omission of the placebo week can be done over an indefinite number of consecutive cycles.

With typical use, approximately 9 out of 100 people who use COCs will become pregnant in the first year.

COCs do not protect against sexually transmitted infections (STIs).

**STANDARD:**

1. (**insert AGENCY name**) MDs, NPs, PAs, DOs, and NDs may prescribe COCs to any client who requests this method and has no U.S. MEC category 4 risk conditions.
2. (**insert AGENCY name**) RNs may dispense COCs to any client who requests this method and has no U.S. MEC category 3 or 4 risk conditions. RNs may dispense COCs to clients with U.S. MEC category 3 conditions only under a current written or verbal order from a prescribing provider.

**PROCEDURE:**

1. Follow the [*Core Reproductive Health Services* *CPS*.](https://www.oregon.gov/oha/PH/HEALTHYPEOPLEFAMILIES/REPRODUCTIVESEXUALHEALTH/RESOURCES/Documents/Clinical-Practice-Standards/CPS-Core_RH.docx)
2. Follow the [U.S. MEC](https://www.cdc.gov/reproductivehealth/contraception/mmwr/mec/appendixd.html) guidelines to determine client eligibility for use of COCs:
3. RNs may initiate the client’s contraceptive method of choice as long as the client has no U.S. MEC category 3 or 4 risk conditions for its use.
4. If client has any MEC category 3 conditions, an NP, PA, DO, ND or MD *may* prescribe the method according to their clinical judgement, if requested by the client. Documentation must show that the client understands the risks of the method and finds other, lower-risk methods unacceptable. RNs may not dispense the method unless under explicit verbal order after discussing the client's case with the prescribing provider.
5. Clients requesting a method for which they have a category 4 risk condition will be offered lower risk methods and referred to an OB/GYN or specialist provider.
6. Each client will receive client instructions regarding warning signs, common side effects, risks, method of use, alternative methods, use of secondary method, and clinic follow-up schedule. Document client education and understanding of the method of choice.

**PLAN:**

1. Initiating combined oral contraceptives:
2. COCs can be initiated at any time if it is reasonably certain that the client is not pregnant.
* If started within the first 5 days since menstrual bleeding started, no additional contraceptive protection is needed.
* If COCs are started > 5 days since menstrual bleeding started, the client needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.
1. RNs may provide up to a 12-month supply of contraception under a standing order/protocol when initiating a method. RNs are allowed to dispense beyond the initial 12 months only if under a current prescription from the clinic’s prescribing provider.
* When the initial start of the method occurs within a visit with a prescribing provider, the provider will write a prescription for up to 1-year supply and may dispense this amount depending on the client’s preference and anticipated use.
* Evidence supports that an extended supply of contraception prevents breaks in use and unintended pregnancy. RNs and providers are encouraged to dispense a 12-month supply whenever possible.
1. Special Considerations:
* Amenorrhea (not postpartum):
1. COCs can be started at any time if it is reasonably certain the client is not pregnant.
2. The client needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.
* Postpartum (breastfeeding):
1. Postpartum clients who are breastfeeding should not use COCs during the first 3 weeks after delivery (category 4) because of concerns of increased risk for venous thromboembolism and generally should not use COCs during the fourth week postpartum (category 3) because of concerns about potential effects on breastfeeding.
2. If the client is < 6 months postpartum, amenorrheic, and fully or nearly fully breastfeeding (exclusively breastfeeding or the vast majority [≥ 85 %] of feeds are breastfeeds), no additional contraceptive protection is needed.
3. A client who is < 21 days postpartum, no additional contraceptive protection is needed.
4. A client who is ≥ 21 days postpartum and has not experienced a return of their menstrual cycle needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.
5. If a client’s menstrual cycle has returned and it has been > 5 days since menstrual bleeding started, the client will need to abstain from intercourse or use additional contraceptive protection for the next 7 days.
* Postpartum (not breastfeeding):
1. Postpartum clients should not use COCs during the first 3 weeks after delivery (Category 4) because of concerns of increased risk for venous thromboembolism. Postpartum clients with other risk factors for venous thromboembolism generally should not use COCs 3-6 weeks after delivery (category 3).
2. A client who is ≥ 21 days postpartum and has not experienced return of their menstrual cycle needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.
3. If a client’s menstrual cycle has returned, and it has been > 5 days since the menstrual bleeding began, the client will need to abstain from sexual intercourse or use additional contraceptive protection for next 7 days.
* Post abortion (spontaneous or induced):
1. COCs can be started within the first 7 days after first or second trimester abortion, including immediately post-abortion (category 1).
2. The client needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days unless COCs are started at the time of the surgical abortion.
3. Switching from another contraceptive method:
4. COCs can be started immediately if it is reasonably certain that the client is not pregnant. Waiting for the next menstrual period is not necessary.
* If it has been > 5 days since menstrual bleeding started, the client needs to abstain from sexual intercourse or use additional contraceptive protection for the next 7 days.
1. Switching from an IUD/IUS:
* If the client has had sexual intercourse since the start of their current menstrual cycle and it has been > 5 days since menstrual bleeding started, theoretically, residual sperm might be in the genital tract. A healthcare provider may consider any of the following options:
1. Advise the client to retain the IUD/IUS for at least 7 days after combined hormonal contraceptives are initiated and return for IUD/IUS removal;
2. Advise the client to abstain from sexual intercourse or use barrier contraceptive for 7 days before removing the IUD/IUS and switching to the new method; advise the client to use ECPs at the time of IUD removal.
3. Combined hormonal contraceptive can be started immediately after use of ECPs (with the exception of Ella®).
4. Combined hormonal contraceptives can be started no sooner than 5 days after use of Ella®.
5. If uncertain whether the client might be pregnant, the benefits of starting COCs likely exceed any risk; therefore, starting COCs should be considered at any time, with a follow-up pregnancy test in 2-4 weeks.

**ROUTINE FOLLOW-UP:**

1. The recommendations listed below address when routine follow-up is recommended for safe and effective continued use of contraception for healthy clients. Although routine follow-up is not necessary for the use of COCs, recommendations might vary for different users and different situations. Specific populations such as adolescents, those with certain medical conditions or characteristics, and those with multiple conditions may benefit from more frequent follow-up visits.
2. Advise the client to return at any time to discuss side effects or other problems or if the client wants to change the method being used.
3. At other routine visits, healthcare providers should do the following:
* Assess the client’s satisfaction with the contraceptive method and whether the client has any concerns about method use;
* Assess any changes in health status, including medications that would change the appropriateness of combined hormonal methods’ safe and effective use based on U.S. MEC;
* Assess blood pressure;
* Consider assessing weight changes and counsel clients who are concerned with any weight changes perceived to be due to contraceptive method; and
* Provide up to the maximum number of refills of the contraceptive method under a current prescription from (**insert AGENCY name**) prescribing provider.

Late or Missed Doses (see **Attachment 1**):

1. Recommendations for late or missed Combined Oral Contraceptives:
2. If one hormonal pill is late (<24 hours since a pill should have been taken), or if one hormonal pill has been missed (24 to <48 hours since a pill should have been taken):
* Take the late or missed pill as soon as possible;
* Continue taking the remaining pills at the usual time (even if it means taking 2 pills on the same day);
* No additional contraceptive protection is needed; and
* EC is not usually needed but can be considered (with the exception of Ella®) if hormonal pills were missed earlier in the cycle or in the last week of the previous cycle.
1. If two or more consecutive hormonal pills have been missed (>48 hours since a pill should have been taken):
* Take the most recent missed pill as soon as possible (any other missed pills should be discarded);
* Continue taking the remaining pills at the usual time (even if it means taking 2 pills on the same day; and
* Use back-up contraception or avoid sexual intercourse until hormonal pills have been taken for 7 consecutive days.
* If pills were missed in the last week of hormonal pills (days 15-21 for 28-day pill pack):
1. Omit the hormone-free interval by finishing the hormonal pills in the current pack and starting a new pack the next day.
2. If unable to start a new pack immediately, use back-up contraception or avoid sexual intercourse until hormonal pills from a new pack have taken for 7 consecutive days.
* EC should be considered (with the exception of Ella®) if hormonal pills were missed during the first week and unprotected sexual intercourse occurred in the previous 5 days.
* EC may also be considered (with the exception of Ella®) at other times as appropriate.

Vomiting or Severe Diarrhea (see **Attachment 2**):

1. Recommendations for vomiting or diarrhea (for any reason, for any duration) that occurs within 24 hours after taking a hormonal pill, or vomiting or diarrhea, for any reason, continuing for 24 to < 48 hours after taking any hormonal pill:
2. Taking another hormonal pill (redose) is unnecessary.
3. Continue taking pills daily at the usual time (if possible, despite discomfort).
4. No additional contraceptive protection is needed.
5. EC is not usually needed but can be considered (with the exception of Ella®) as appropriate.
6. Recommendations for vomiting or diarrhea, for any reason, continuing for ≥ 48 hours after taking any hormonal pill:
7. Continue taking pills daily at the usual time (if possible, despite discomfort).
8. Use back-up contraception or avoid sexual intercourse until hormonal pills have been taken for 7 consecutive days after vomiting or diarrhea has resolved.
9. If vomiting or diarrhea occurred in the last week of hormonal pills (days 15-21 for 28-day pill packs):
* Omit the hormone-free interval by finishing the hormonal pills in the current pack and starting a new pack the next day.
* If unable to start a new pack immediately, use back-up contraception or avoid sexual intercourse until hormonal pills from a new pack have been taken for 7 consecutive days.
1. EC should be considered (with the exception of Ella®) if vomiting or diarrhea occurred within the first week of a new pill pack and unprotected sexual intercourse occurred in the previous 5 days.
2. EC may also be considered (with the exception of Ella®) at other times as appropriate.

Extended/Continuous Use of Combined Oral Contraceptives:Unscheduled Bleeding

1. Extended contraceptive use is defined as a planned hormone-free interval after at least two contiguous cycles.
2. Continuous contraceptive use is defined as uninterrupted use of hormonal contraception without a hormone-free interval.
3. Before initiation of combined oral contraceptives, provide counseling about potential changes in bleeding patterns during extended or continuous use.
4. Unscheduled spotting or bleeding is common during the first 3-6 months of extended or continuous combined hormonal use. It is not harmful and typically decreases with continued use.
5. If clinically indicated, consider an underlying gynecological problem (e.g., STI, pregnancy or new pathologic uterine conditions). Refer to the prescribing provider/primary care provider for evaluation.
6. If an underlying gynecological problem is not found and the client wants treatment, the following treatment option can be considered:
* Advise the client to discontinue combined hormonal contraceptive use for 3-4 consecutive days. A hormone-free interval is not recommended during the first 21 days of using the continuous or extended combined hormonal contraceptive method. A hormone-free interval also is not recommended more than once per month because contraceptive effectiveness might be reduced.
* If unscheduled spotting or bleeding persists and the client finds it unacceptable, counsel client on alternative contraceptive methods, and offer another method if it is desired.

**STOPPING THE COMBINED ORAL CONTRACTIVES:**

1. Combined hormonal contraceptives may be stopped at any time.
2. Fertility will return rapidly.
3. If client does not want to be pregnant, advise the client to begin a new contraceptive method immediately.
4. If client desires to be pregnant:
5. Provide the client with preconception counseling; and
6. Advise client to begin taking a daily prenatal vitamin with 0.4 to 0.8 milligrams of folic acid at least 30 days before trying to become pregnant.

**CLIENT EDUCATION:**

1. Advise the client that combined hormonal contraceptive may change their periods; the client may have spotting or irregular bleeding for the first few months.
2. Advise the client to call the clinic if they have any questions or concerns regarding the contraceptive method.
3. Inform the client that any signs or symptoms of complications should be reported to the clinic; if the clinic is not open, clients should call 911 or go to the emergency room.
4. Advise the client the warning signs of ACHES (client should be informed to seek immediate care if any warning signs are noted):
5. Abdominal pain;
6. Chest pain;
7. Headaches;
8. Eye problems; and/or
9. Severe leg pain.

**REFERENCES:**

Centers for Disease Control and Prevention. 2016. U.S. Medical Eligibility Criteria for Contraceptive Use, 2016. <https://www.cdc.gov/mmwr/volumes/65/rr/pdfs/rr6503.pdf>

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**ATTACHMENT 1: Recommended Actions After Late or Missed Combined Oral Contraceptives**

If two or more consecutive hormonal pills have been missed: (≥48 hours since a pill should have been taken).

If one hormonal pill has been missed: (24 to <48 hours since a pill should have been taken)

If one hormonal pill is late:

(<24 hours since a pill should have been taken)

* Take the late or missed pill as soon as possible.
* Continue taking the remaining pills at the usual time (even if it means taking two pills on the same day).
* No additional contraceptive protection is needed.
* Emergency contraception is not usually needed but can be considered (with the exception of Ella®) if hormonal pills were missed earlier in the cycle or in the last week of the previous cycle.
* Take the most recent missed pill as soon as possible. (Any other missed pills should be discarded.)
* Continue taking the remaining pills at the usual time (even if it means taking two pills on the same day).
* Use back-up contraception (e.g. condoms) or avoid sexual intercourse until hormonal pills have been taken for 7 consecutive days.
* If pills were missed in the last week of hormonal pills (e.g., days 15-21 for 28-day pill packs):
* Omit the hormone-free interval by finishing the hormonal pills in the current pack and starting a new pack the next day.
* If unable to start a new pack immediately, use back-up contraception (e.g., condoms) or avoid sexual intercourse until hormonal pills from a new pack have been taken for 7 consecutive days.
* Emergency contraception should be considered (with the exception of Ella®) if hormonal pills were missed during the first week and unprotected sexual intercourse occurred in the previous 5 days.
* Emergency contraception may also be considered (with the exception of Ella®) at other times as appropriate.

**ATTACHMENT 2: Recommended Steps After Vomiting or Diarrhea While Using Combined Oral Contraceptives**

Vomiting or diarrhea, for any reason, continuing for ≥48 hours after taking any hormonal pill

Vomiting diarrhea, for any reason, continuing for 24 to 48 hours after taking any hormonal pill

Vomiting or diarrhea (for any reason, for any duration), that occurs within 24 hours after taking a hormonal pill

* Taking another hormonal pill (redoes) is unnecessary.
* Continue taking pills daily at the usual time (if possible, despite discomfort).
* No additional contraceptive protection is needed.
* Emergency contraception is not usually needed but can be considered (with the exception of Ella®) as appropriate.
* Continue taking pills daily at the usual time (if possible, despite discomfort).
* Use back-up contraception (e.g., condoms) or avoid sexual intercourse until hormonal pills have been taken for 7 consecutive days after vomiting or diarrhea has resolved.
* If vomiting or diarrhea occurred in the last week of hormonal pills (e.g., days 15-21 for 28-day pill packs):
* Omit the hormone-free interval by finishing the hormonal pills in the current pack and start a new pack the next day.
* If unable to start a new pack immediately, use back-up contraception (e.g., condoms) or avoid sexual intercourse until hormonal pills from a new pack have been taken for 7 consecutive days.
* Emergency contraception should be considered (with the exception of Ella®) if vomiting or diarrhea occurred within the first week of a new pill pack and unprotected sexual intercourse occurred in the previous 5 days.
* Emergency contraception may also be considered (with the exception of Ella®) at other times as appropriate.