#### Webinar Q&A

# What's New in the 2024 U.S. Medical Eligibility Criteria for Contraceptive Use (U.S. MEC), Selected Practice Recommendations for Contraceptive Use (U.S. SPR), and Quality Family Planning (QFP) Guidelines June 24, 2025

#### 1. Are there any updates or contraindications for Annovera®?

Annovera® is a Family Planning, Access, Care, and Treatment (Family PACT) Program benefit. Nothing has changed in the patient package insert regarding indications or contraindications.

#### 2. Is Annovera® still considered a long-acting reversible contraceptive (LARC)?

The company that markets Annovera® promoted it as being a LARC method, but it was never considered to be a LARC by family planning experts, even though it works for 1 year. The original definition of long-acting reversible contraceptives (i.e., intrauterine devices (IUDs) and implants) had to do with the fact that they are "forgettable contraceptives." Once the implant or IUD is placed, a person can forget about their need for contraception, unless they are having side effects, desire early removal, or until the IUD or implant expires and it needs to be exchanged.

That is not the case with Annovera®, because it can be self-removed for cleaning or for intercourse. Within 2 hours of removal, it should be washed and reinserted. Because of this, it's not appropriate to consider the method to be "forgettable," like IUDs and implants.

#### 3. Is there a simplified list of the U.S. MEC/U.S. SPR changes?

Yes. Appendix A in the U.S. MEC lists all the changes in 2024 compared to 2016. It can be found at https://www.cdc.gov/contraception/hcp/usmec/changes-from-2016.html.

4. Why does the U.S. Centers for Disease Control and Prevention (CDC) say levonorgestrel (LNG-IUDs) need a barrier method as a backup for 7 days? Yes, if Kyleena®, but for Mirena®/LILETTA®, I thought it was effective immediately, like for the copper IUD? And also, is it okay to use for emergency contraception?

The 2024 U.S. SPR states the following regarding the need for back-up contraception:

- If the LNG-IUD is placed within the first 7 days since menstrual bleeding started, no additional contraceptive protection is needed.
- If the LNG-IUD is placed >7 days since menstrual bleeding started, the patient needs to abstain from sexual intercourse or use barrier methods (e.g., condoms) for the next 7 days.

Reference - CDC Intrauterine Contraception: https://www.cdc.gov/contraception/hcp/usspr/intrauterine-contraception.html

### 5. Are there updated recommendations for sickle cell trait (SCT) (not just sickle cell disease (SCD)?

No, not in the U.S. MEC and U.S. SPR. The updated recommendations apply to people with homozygous (hemoglobin SS) SCD. There is no mention of contraceptive method restrictions for people with SCT. Having SCT simply means that a person carries a single gene for SCD and can pass this gene along to their children. People with SCT usually do not have any of the symptoms of SCD and live a normal life.

## 6. Do you need to check kidney functions first prior to initiation of birth control, given new data on chronic kidney disease?

No. There is no recommendation to routinely screen healthy people for chronic kidney disease.

### 7. Can you share the link to the slide on when to start specific contraceptive methods?

Reference - When to Start Using Specific Contraceptive Methods: <a href="https://www.cdc.gov/contraception/media/pdfs/2024/07/when-to-start-contraception-508.pdf">https://www.cdc.gov/contraception/media/pdfs/2024/07/when-to-start-contraception-508.pdf</a>

## 8. Regarding peripartum cardiomyopathy, which birth control method has more concern about safety?

For people with peripartum cardiomyopathy and normal or mildly impaired cardiac function, combined hormonal contraceptives (CHCs) are **U.S. MEC-4** if the person has had the condition for < 6 months and **U.S. MEC-3** if  $\ge 6$  months.

For people with peripartum cardiomyopathy and moderately or severely impaired cardiac function, CHCs are **U.S. MEC-4** and depot medroxyprogesterone acetate (DMPA) is **U.S. MEC-3** if  $\geq$  6 months. All other prescription methods are **U.S. MEC-2**.

9. Will there be new, updated U.S. MEC wheels? I find those really helpful to share with patients.

It's unknown if the CDC plans to update this product. Updated 2024 U.S. MEC and U.S. SPR job aids can be found at: https://www.cdc.gov/contraception/hcp/provider-tools/.

### 10. For the increased risk of venous thromboembolism with DMPA, is this increased for Factor V?

Yes. For people with thrombophilias, including Factor V Leiden mutation, prothrombin gene mutation, protein S, protein C, and antithrombin deficiencies, or antiphospholipid syndrome, CHCs are **U.S. MEC-4**, and DMPA is **U.S. MEC-3**. Other hormonal methods are **U.S. MEC-2**, and copper IUDs are **U.S. MEC-1**.

11. Do we know when the U.S. Food and Drug Administration (FDA) will update the indications for Paragard® to 12 years, Mirena® to 8 years, and Nexplanon® to 5 years?

The patient package insert (PPI) for Paragard® still lists a duration of 10 years, even though several studies have shown that it works for much longer. The PPIs for Mirena® and for LILETTA® have been updated and list a duration of 8 years. The PPI for Nexplanon® states that the duration is 3 years, but studies have shown that it works for at least 5 years.

12. Does the 2024 U.S. MEC comment on risks with emergency contraception use (ella® or Plan B), or should we just extrapolate that if there are no progestin contraindications, they are okay to use?

Both the U.S. MEC and U.S. SPR have updated information about emergency contraceptives.

Reference - U.S. MEC: Appendix J: Classifications for Emergency Contraception. Found at <a href="https://www.cdc.gov/contraception/hcp/usmec/emergency-contraception.html">https://www.cdc.gov/contraception/hcp/usmec/emergency-contraception.html</a>
U.S. SPR: <a href="https://www.cdc.gov/contraception/hcp/usspr/emergency-contraception.html">https://www.cdc.gov/contraception/hcp/usspr/emergency-contraception.html</a>

# 13. The CDC Contraception App is great. There is a U.S. MEC condition for obesity above a body mass index (BMI) of 30. Are there any category guidelines for BMI > 40?

There are no specific guidelines in the U.S. MEC/U.S. SPR for other (higher) BMI categories.

# 14. Should I then treat all obese patients with a BMI > 30 the same, regardless of whether they are morbidly obese?

Yes, according to the 2024 U.S. MEC, CHCs are **U.S. MEC-2**, because both obesity and estrogen-containing contraceptives are risk factors for venous complications. The 2024 U.S. MEC points out that additional risk factors, such as age  $\geq$  40, diabetes, smoking, and family history of thrombosis, increase the risk of deep vein thrombosis (DVT) and pulmonary embolism (PE) even more, and that CHCs might increase thrombosis risk to an unacceptable level.

An American College of Obstetricians and Gynecologists (ACOG) Practice Bulletin #206 (2019) on Use of Hormonal Contraception in Women with Coexisting Medical Conditions states that consideration should be given to the use of IUDs and progestinonly contraceptives when counseling women with obesity regarding contraceptive choices, especially among those older than 35 years of age.

Reference - ACOG Practice Bulletin #206: https://pubmed.ncbi.nlm.nih.gov/30681544/

#### 15. Is pre-exposure prophylaxis (PrEP) included in this?

PrEP is not in either of the CDC contraceptive guidelines.

# 16. Thank you for the information and changes concerning thrombotic risks. Does it matter if a patient is taking one of the antithrombotic medications (e.g., Dabigatran)?

The 2024 U.S. MEC does address the use of hormonal contraceptives in women who are taking anticoagulation medications.

- For people who have recently had a DVT or pulmonary embolism and are receiving anticoagulant therapy and are in the therapeutic range, CHCs are **U.S. MEC-3**, and all other methods are **U.S. MEC-2**.
- For those with a history of DVT/PE who are using prophylactic regimens of anticoagulant drugs, the recommendations are divided between those at higher risk of recurrent DVT/PE and those with no risk factors. Please check the CDC U.S.
   MEC/U.S. SPR app for a listing of relevant risk factors for recurrent DVT/PE and the

U.S. MEC categories of contraceptives, which differ in those with risk factors and those without.

# 17. Can you speak to contraceptive efficacy as related to Ozempic®/Wegovy®/similar medications? Do these medications affect only oral contraceptives?

You can review this table at the following location:

Reference - Possible Drug Interaction Between GLP-1 Agonist and Oral Contraceptives: <a href="https://www.reproductiveaccess.org/resource/possible-drug-interaction-between-glp-1-agonist-and-oral-contraceptives/">https://www.reproductiveaccess.org/resource/possible-drug-interaction-between-glp-1-agonist-and-oral-contraceptives/</a>

#### 18. Is Opill® covered by Family PACT?

Opill® is the over-the-counter (OTC) norgestrel progestin-only pill. It is covered by Family PACT and Medi-Cal, but it requires a prescription. This is counterintuitive since the whole point of Opill® is that it is the first OTC birth control pill, but a prescription is how the person can use their Medi-Cal or Family PACT coverage:

- a. Medi-Cal Rx Contract Drugs List Over-the-Counter Drugs and Cough/Cold <u>Preparations</u> [CTRL+F to find or search for norgestrel]
- b. We are in the process of working with the Pharmacy Benefits Division to update page 3 of <a href="Medi-Cal Rx Family Planning">Medi-Cal Rx Family Planning</a>, Access, Care, and Treatment <a href="Pharmacy Formulary">Pharmacy Formulary</a> to make it clear that providers should go to the OTC Contract Drugs List for Opill®/norgestrel.

It may be helpful to think of this as just like getting coverage for other OTC medications, like ibuprofen. Even though someone can buy it OTC, to make sure that Family PACT and Medi-Cal know to pay, the provider needs to write the prescription.

#### **Depot Medroxyprogesterone Acetate (DMPA) Questions**

19. Is there an increased risk of venous thromboembolism (VTE) or history of venous thromboembolism, or both, for DMPA?

There is an increased risk of VTE with DMPA, especially for people with a history of previous VTE.

20. Regarding Depo for high BMI, what about someone younger than 35, and also if someone is on testosterone (lowered risk of venous thromboembolism)?

There is no contraindication for BMI and DMPA intramuscular (DMPA-IM) or DMPA subcutaneous (DMPA-SC). Taking concurrent testosterone does not change this risk.

# 21. Please discuss meningioma risk with Depo-Provera®. Do you have any information about how to counsel patients on the study that states DMPA leads to benign brain tumors?

The U.S. MEC does not give guidance on meningioma and DMPA because there is not enough data. A study from 2024 (REFERENCE: Roland N, Neumann A, Hoisnard L, et al. Use of progestogens and the risk of intracranial meningioma: national case-control study [published correction appears in BMJ. 2024 Mar 28;384:q776. doi: 10.1136/bmj.q776.]. BMJ. 2024;384:e078078. Published 2024 Mar 27. doi:10.1136/bmj-2023-078078) showed a small increase in the relative risk of meningioma with prolonged use of DMPA. However, the absolute risk is small, and the study did not evaluate continuation of DMPA if diagnosed with meningioma. This case-control study, while fairly large, is not an ideal study from an epidemiologic point of view. The study observed that DMPA was associated with the development of a particular type of brain tumor, a central nervous system (CNS) tumor, which is called a meningioma. Meningiomas do not occur in the parenchyma of the brain itself but in the meninges, which are the covering of the brain, and they are benign. When that study came out, there was a lot of criticism of it, both for its methodology, which was not great, and the fact that in this subgroup of people who were using Depo-Provera®, the numbers weren't very high in making this epidemiologic association between meningiomas and Depo-Provera®.

The reason why you're seeing a lot about it on places like Facebook and on social media is that plaintiffs' lawyers are trying to find people who may have had that problem, and then they'll be filing product liability lawsuits about it. But at least in the medical community, we weren't very impressed by it.

Also, it is worth noting that if somebody has a meningioma already, there was no observation of whether DMPA is contraindicated for use. There was no clinical association with the meningiomas getting larger, and they didn't have the power to even look at that. The reason why the CDC did not provide guidance on this is that there just isn't enough of an evidence base to suggest that it should be a higher risk category. When this comes up with clients in a clinic, we usually share this information with the clients and then allow them to decide about the benefits that they're going to gain from DMPA, and then the risks that they feel from a benign meningioma.

22. Just confirming both routes have wiggle room of 1-2 weeks, just in case the patient misses a dose, they do NOT need a backup method.

Yes.

23. If blood pressure isn't a required test to start someone on Depo-Provera®, would the risk of someone having a blood pressure (BP) over 160/100 be fairly rare (with no hypertension (HTN) history)? We are trying to remove barriers for patients to have to be in person and do BP for something like a Depo-Provera® start.

No, because the pathophysiology of the clotting is not due to blood pressure or increased blood pressure. Those things are not related. You really think about blood pressure with the estrogen component.

24. Pfizer says, "Depo-subQ Provera 104 is only for subcutaneous administration and is only to be administered by a healthcare professional." But this is prescribed for client administration.

We know from multiple studies that DMPA-SC for self-administration is safe, effective, and in many cases leads to longer continuation rates than DMPA-IM for those who want to take it. The label will not likely change anytime soon, given the cost of changing the label.

#### 25. Is the DMPA-SQ still every 3 months?

It is every 12 or 13 weeks. The interval that is recommended for Depo-subQ Provera 104® (Depo-subQ) compared to Depo-Provera® IM is every 12 weeks, but you have a grace period of two weeks. Ideally, set your calendar to provide a subcutaneous injection every 12 weeks because that is simple, and then if a client misses their injection date, they have a 2-week grace period. They just give themselves an injection as soon as they remember and then restart the clock. Also worth noting is that people who are candidates for DMPA-SC are also candidates for DMPA-IM. The formulation itself doesn't change the contraindications, the side effects, or who qualifies as a good candidate. When you are talking to your clients, provide patient-centered counseling and ask whether they're interested in self-administering the injection or coming to the clinic to receive the injection. Clients will have reasons for their preference.

#### 26. Are there any guidelines for patients to give themselves DMPA-SQ at home?

There are no national guidelines, but the Clinical Training Center for Sexual and Reproductive Health has a toolkit. It includes evidence-based guidance about how to talk about DMPA-SQ with clients and contains resources for both providers and clients. For example, there are videos in English and Spanish, and written materials in different languages that you can share with your clients.

Reference - A Toolkit for Self-Administration of Subcutaneous Depot Medroxyprogesterone Acetate: <a href="https://ctcsrh.org/RiseToolkit1/content/#/">https://ctcsrh.org/RiseToolkit1/content/#/</a>

#### 27. How long post abortion are those concerns about DMPA relevant?

The concern is that the progesterone in the DMPA will block the anti-progesterone effects of mifepristone and make the medication abortion (MAB) less effective. In reality, if a client takes mifepristone, the mifepristone works within 24 hours. So, DMPA could be started 24 hours later without any theoretical interference, decreasing mifepristone's effectiveness. In addition, remember that misoprostol-only MABs are highly effective. So, you can weigh the ability of the client returning after 24 hours for DMPA or provide them with self-administered DMPA, which they can give after 24 hours of mifepristone. But, also, the risk is still only a **U.S. MEC-2** and is ONLY theoretical and has not been borne out in practice to significantly decrease the effectiveness of mifepristone if providing DMPA at the same time as mifepristone ingestion.

#### 28. Is DMPA-IM or DMPA-SC more effective?

They are equally effective if used correctly and consistently.

# 29. These resources were once restricted from the CDC website by federal guidance and rules. Are you confident that access will not be impacted again?

The CDC is changing the language in the U.S. MEC and U.S. SPR to be consistent with presidential executive orders on Diversity, Equity, and Inclusion (DEI) terminology. Once that process is completed, job aids are expected to be reposted. Neither of us has any information about when this might occur.

One of the important things is that you can get the original documents from the <u>familypact.org</u> website. <u>The Society of Family Planning</u> (SFP) and <u>ACOG</u> also make them available on their websites without a password.