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# U.S. Medical Eligibility Criteria for Contraceptive Use, 2016



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## U.S. Medical Eligibility Criteria for Contraceptive Use, 2016

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#### **Summary**

The 2016 U.S. Medical Eligibility Criteria for Contraceptive Use (U.S. MEC) comprises recommendations for the use of specific contraceptive methods by women and men who have certain characteristics or medical conditions. These recommendations for health care providers were updated by CDC after review of the scientific evidence and consultation with national experts who met in Atlanta, Georgia, during August 26–28, 2015. The information in this report updates the 2010 U.S. MEC (CDC. U.S. medical eligibility criteria for contraceptive use, 2010. MMWR 2010:59 [No. RR-4]). Notable updates include the addition of recommendations for women with cystic fibrosis, women with multiple sclerosis, and women receiving certain psychotropic drugs or St. John's wort; revisions to the recommendations for emergency contraception, including the addition of ulipristal acetate; and revisions to the recommendations for postpartum women; women who are breastfeeding; women with known dyslipidemias, migraine headaches, superficial venous disease, gestational trophoblastic disease, sexually transmitted diseases, and human immunodeficiency virus; and women who are receiving antiretroviral therapy. The recommendations in this report are intended to assist health care providers when they counsel women, men, and couples about contraceptive method choice. Although these recommendations are meant to serve as a source of clinical guidance, health care providers should always consider the individual clinical circumstances of each person seeking family planning services. This report is not intended to be a substitute for professional medical advice for individual patients. Persons should seek advice from their health care providers when considering family planning options.

#### Introduction

Approximately 45% of all pregnancies that occur in the United States are unintended (1), with associated increased risks for adverse maternal and infant health outcomes (2) and increased health care costs (3). Women, men, and couples have increasing numbers of safe and effective choices for contraceptive methods, including long-acting reversible contraception methods such as intrauterine devices (IUDs) and implants, to reduce the risk for an unintended pregnancy. However, with these expanded options comes the need for evidence-based guidance to help health care providers offer quality family planning care to their patients, including choosing the most appropriate contraceptive method for

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individual circumstances and using that method correctly, consistently, and continuously to maximize effectiveness.

In 2010, CDC published the first U.S. Medical Eligibility Criteria for Contraceptive Use (U.S. MEC), which provided recommendations on safe use of contraceptive methods for women with various medical conditions and other characteristics (and was adapted from global guidance developed by the World Health Organization [WHO MEC]) (4,5). U.S. MEC is a companion document to the U.S. Selected Practice Recommendations for Contraceptive Use (U.S. SPR), which provides guidance on how to use contraceptive methods safely and effectively once they are deemed to be medically appropriate (6). WHO intended for the global guidance to be used by local or national policy makers, family planning program managers, and the scientific community as a reference when they develop family planning guidance at the country or program level. During 2008-2010, CDC participated in a formal process to adapt the global guidance for appropriateness

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for use in the United States, which included rigorous identification and critical appraisal of the scientific evidence through systematic reviews, and input from national experts on how to translate that evidence into recommendations for U.S. health care providers (5). At that time, CDC committed to keeping this guidance up to date and based on the best available evidence, with full review every few years (5).

This document updates CDC's U.S. MEC 2010 (5), based on new evidence and input from experts. A summary of changes from U.S. MEC 2010 is provided (Appendix A). Notable updates include the following:

- addition of recommendations for women with cystic fibrosis, women with multiple sclerosis, and women receiving certain psychotropic drugs or St. John's wort
- revisions to the recommendations for emergency contraception, including the addition of ulipristal acetate
- revisions to the recommendations for postpartum women; women who are breastfeeding; women with known dyslipidemias, migraine headaches, superficial venous disease, gestational trophoblastic disease, sexually transmitted diseases (STDs), and human immunodeficiency virus (HIV); and women who are receiving antiretroviral therapy

The goal of these recommendations is to remove unnecessary medical barriers to accessing and using contraception, thereby decreasing the number of unintended pregnancies. These recommendations are meant to serve as a source of clinical guidance for health care providers; health care providers should always consider the individual clinical circumstances of each person seeking family planning services. This report is not intended to be a substitute for professional medical advice for individual patients, who should seek advice from their health care providers when considering family planning options.

#### **Methods**

Since publication of U.S. MEC 2010, CDC has monitored the literature for new evidence relevant to the recommendations through the WHO/CDC continuous identification of research evidence (CIRE) system. This system identifies new evidence as it is published and allows WHO and CDC to update systematic reviews and facilitate updates to recommendations as new evidence warrants. Automated searches are run in PubMed weekly, and the results are reviewed. Abstracts that meet specific criteria are added to the web-based CIRE system, which facilitates coordination and peer review of systematic reviews for both WHO and CDC (7). In 2014, CDC reviewed all of the existing recommendations in U.S. MEC 2010 for new evidence identified by CIRE that had the potential to lead to a changed recommendation. During August 27–28,

2014, CDC held a meeting in Atlanta, Georgia, of 11 family planning experts and representatives from partner organizations to solicit their input on the scope of and process for updating both U.S. MEC 2010 and U.S. SPR 2013. The participants were experts in family planning and represented various types of health care providers, as well as health care provider organizations. A list of participants is provided at the end of this report. Meeting participants discussed topics to be addressed in the update of U.S. MEC based on new evidence published since 2010 (identified through the CIRE system), topics addressed at a 2014 WHO meeting to update global guidance, and suggestions CDC received from health care providers for the addition of recommendations for women with medical conditions not yet included in U.S. MEC (e.g., from provider feedback through e-mail, public inquiry, and questions received at conferences). CDC identified several topics to consider when updating the guidance, including revision of existing recommendations for certain medical conditions or characteristics (breastfeeding, postpartum, HIV, receiving antiretroviral therapy, obesity, dyslipidemia, increased risk for STDs, superficial venous thrombosis, gestational trophoblastic disease, and migraine headaches), addition of recommendations for new medical conditions (cystic fibrosis, multiple sclerosis, use of certain psychotropic drugs, and St. John's wort), and addition of recommendations for new contraceptive methods (ulipristal acetate for emergency contraception). CDC determined that all other recommendations in U.S. MEC 2010 were up to date and consistent with the existing body of evidence for that recommendation.

In preparation for a subsequent expert meeting held during August 26-28, 2015, to review the scientific evidence for potential recommendations, CDC staff members and other invited authors listed at the end of this report conducted independent systematic reviews for each of the topics being considered. The purpose of these systematic reviews was to identify direct evidence about the safety of contraceptive method use by women with selected conditions (e.g., risk for disease progression or other adverse health effects in women with multiple sclerosis who use combined hormonal contraceptives [CHCs]). Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines were followed for reporting systematic reviews (8,9), and strength and quality of the evidence were assigned using the system of the U.S. Preventive Services Task Force (10). When direct evidence was limited or not available, indirect evidence (e.g., evidence on surrogate outcomes or among healthy women) and theoretical issues were considered and either added to direct evidence within a systematic review or separately compiled for presentation to the meeting participants. Completed systematic reviews were peer reviewed by two or three experts and then provided to participants before the expert meeting. Reviews are referenced and cited throughout this document; the full reviews appear in the published literature and contain the details of each review, including the systematic review question, literature search protocol, inclusion and exclusion criteria, evidence tables, and quality assessments. CDC staff continued to monitor new evidence identified through the CIRE system during the preparation for the August 2015 meeting.

During August 26-28, 2015, in Atlanta, Georgia, CDC held a meeting with 44 participants who were invited to provide their individual perspectives on the scientific evidence presented and potential recommendations. Twenty-nine of the participants represented a wide range of expertise in family planning provision and research, and included obstetricians/ gynecologists, pediatricians, family physicians, nurse practitioners, epidemiologists, and others with research and clinical practice expertise in contraceptive safety, effectiveness, and management; these individuals participated in the entire meeting. Fifteen participants with expertise relevant to specific topics on the meeting agenda provided information and participated in the discussion (e.g., an expert in cystic fibrosis was asked to provide general information about the condition and to assist in interpreting the evidence and any theoretical concerns on the use of contraceptive methods in women with the condition); these participants provided input only during the session for which their topics were discussed. Lists of participants and any potential conflicts of interest are provided at the end of this report. During the meeting, the evidence from the systematic review for each topic was presented, including direct evidence and any indirect evidence or theoretical concerns. Participants provided their perspectives on using the evidence to develop recommendations that would meet the needs of U.S. health care providers. After the meeting, CDC determined the recommendations in this report, taking into consideration the perspectives provided by the meeting participants. Feedback also was received from three external reviewers, composed of health care providers and researchers who had not participated in the update meetings. These reviewers were asked to provide comments on the accuracy, feasibility, and clarity of the recommendations. Areas of research that need additional investigation also were considered during the meeting (11).

#### **How to Use This Document**

These recommendations are intended to help health care providers determine the safe use of contraceptive methods among women and men with various characteristics and

medical conditions. Providers also can use the information in these recommendations when consulting with women, men, and couples about their selection of contraceptive methods. The tables in this document include recommendations for the use of contraceptive methods by women and men with particular characteristics or medical conditions. Each condition is defined as representing either an individual's characteristics (e.g., age or history of pregnancy) or a known preexisting medical or pathologic condition (e.g., diabetes or hypertension). The recommendations refer to contraceptive methods being used for contraceptive purposes; the recommendations do not consider the use of contraceptive methods for treatment of medical conditions because the eligibility criteria in these situations might differ. The conditions affecting eligibility for the use of each contraceptive method are classified into one of four categories (Box 1).

#### **Using the Categories in Practice**

Health care providers can use the eligibility categories when assessing the safety of contraceptive method use for women and men with specific medical conditions or characteristics. Category 1 comprises conditions for which no restrictions exist for use of the contraceptive method. Classification of a method/condition as category 2 indicates the method generally can be used, although careful follow-up might be required. For a method/condition classified as category 3, use of that method usually is not recommended unless other more appropriate methods are not available or acceptable. The severity of the condition and the availability, practicality, and acceptability of alternative methods should be considered, and careful follow-up is required. Hence, provision of a contraceptive method to a woman with a condition classified as category 3 requires careful clinical judgement and access to clinical services. Category 4 comprises conditions that represent an unacceptable health risk if the method is used. For example, a smoker aged <35 years generally can use combined oral contraceptives (COCs) (category 2). However, for a woman

#### $BOX\ 1.\ Categories\ of\ medical\ eligibility\ criteria\ for\ contraceptive\ use$

- 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.

aged ≥35 years who smokes <15 cigarettes per day, the use of COCs usually is not recommended unless other methods are not available or acceptable to her (category 3). A woman aged ≥35 years who smokes ≥15 cigarettes per day should not use COCs because of unacceptable health risks, primarily the risk for myocardial infarction and stroke (category 4). The programmatic implications of these categories might depend on the circumstances of particular professional or service organizations. For example, in some settings, a category 3 might mean that a special consultation is warranted.

The recommendations address medical eligibility criteria for the initiation and continued use of all methods evaluated. The issue of continuation criteria is clinically relevant whenever a medical condition develops or worsens during use of a contraceptive method. When the categories differ for initiation and continuation, these differences are noted in the Initiation and Continuation columns. When initiation and continuation are not indicated, the category is the same for initiation and continuation of use.

On the basis of this classification system, the eligibility criteria for initiating and continuing use of a specific contraceptive method are presented in tables (Appendices A-K). In these tables, the first column indicates the condition. Several conditions are divided into subconditions to differentiate between varying types or severity of the condition. The second column classifies the condition for initiation or continuation (or both) into category 1, 2, 3, or 4. For certain conditions, the numeric classification does not adequately capture the recommendation; in these cases, the third column clarifies the numeric category. These clarifications were determined during the discussions of the scientific evidence and are considered a necessary element of the recommendation. The third column also summarizes the evidence for the recommendation if evidence exists. The recommendations for which no evidence is cited are based on expert opinion from either the WHO or U.S. expert meeting in which these recommendations were developed, and might be based on evidence from sources other than systematic reviews. For certain recommendations, additional comments appear in the third column and generally come from the WHO meeting or the U.S. meeting.

# Recommendations for Use of Contraceptive Methods

The classifications for whether women with certain medical conditions or characteristics can use specific contraceptive methods are provided for intrauterine contraception, including the copper-containing IUD and levonorgestrel-releasing IUDs

(Appendix B); progestin-only contraceptives (POCs), including etonogestrel implants, depot medroxyprogesterone acetate injections, and progestin-only pills (Appendix C); CHCs, including low-dose (containing ≤35 µg ethinyl estradiol) COCs, combined hormonal patch, and combined vaginal ring (Appendix D); barrier contraceptive methods, including male and female condoms, spermicides, diaphragm with spermicide, and cervical cap (Appendix E); fertility awareness—based methods (Appendix F); lactational amenorrhea method (Appendix G); coitus interruptus (Appendix H); female and male sterilization (Appendix I); and emergency contraception, including emergency use of the copper-containing IUD and emergency contraceptive pills (Appendix J). A table at the end of this report summarizes the classifications for the hormonal and intrauterine methods (Appendix K).

#### **Contraceptive Method Choice**

Many elements need to be considered by women, men, or couples at any given point in their lifetimes when choosing the most appropriate contraceptive method. These elements include safety, effectiveness, availability (including accessibility and affordability), and acceptability. The guidance in this report focuses primarily on the safety of a given contraceptive method for a person with a particular characteristic or medical condition. Therefore, the classification of category 1 means that the method can be used in that circumstance with no restrictions with regard to safety but does not necessarily imply that the method is the best choice for that person; other factors, such as effectiveness, availability, and acceptability, might play an important role in determining the most appropriate choice. Voluntary informed choice of contraceptive methods is an essential guiding principle, and contraceptive counseling, when applicable, might be an important contributor to the successful use of contraceptive methods.

In choosing a method of contraception, dual protection from the simultaneous risk for HIV and other STDs also should be considered. Although hormonal contraceptives and IUDs are highly effective at preventing pregnancy, they do not protect against STDs, including HIV. Consistent and correct use of the male latex condom reduces the risk for HIV infection and other STDs, including chlamydial infection, gonococcal infection, and trichomoniasis (12). Although evidence is limited, use of female condoms can provide protection from acquisition and transmission of STDs (12). All patients, regardless of contraceptive choice, should be counseled about the use of condoms and the risk for STDs, including HIV infection (12). Additional information about prevention and treatment of STDs is available from the CDC Sexually Transmitted Diseases Treatment Guidelines (http://www.cdc.gov/std/treatment) (12).

#### **Contraceptive Method Effectiveness**

Contraceptive method effectiveness is critical for minimizing the risk for an unintended pregnancy, particularly among women for whom an unintended pregnancy would pose additional health risks. The effectiveness of contraceptive methods depends both on the inherent effectiveness of the method itself and on how consistently and correctly it is used (Figure). Methods that depend on consistent and correct use have a wide range of effectiveness. IUDs and implants are considered long-acting, reversible contraception (LARC); these methods are highly effective because they do not depend on regular compliance from the user. LARC methods are appropriate for most women, including adolescents and nulliparous women. All women should be counseled about the full range and effectiveness of contraceptive options for which they are medically eligible so that they can identify the optimal method.

#### Unintended Pregnancy and Increased Health Risk

For women with conditions that might make pregnancy an unacceptable health risk, long-acting, highly effective contraceptive methods might be the best choice to avoid unintended pregnancy (Figure). Women with these conditions should be advised that sole use of barrier methods for contraception and behavior-based methods of contraception might not be the most appropriate choice because of their relatively higher typical-use rates of failure (Figure). Conditions included in U.S. MEC that are associated with increased risk for adverse health events as a result of pregnancy are identified throughout the document (Box 2). Some of the medical conditions included in U.S. MEC recommendations are treated with teratogenic drugs. While the woman's medical condition may not affect her eligibility to use certain contraceptive methods, women using teratogenic drugs are at increased risk for poor pregnancy outcomes; long-acting, highly effective contraceptive methods might be the best option to avoid unintended pregnancy or delay pregnancy until teratogenic drugs are no longer needed.

#### **Keeping Guidance Up to Date**

Updating the evidence-based recommendations as new scientific evidence becomes available is a challenge. CDC will continue to work with WHO to identify and assess new relevant evidence as it becomes available and to determine whether changes in the recommendations are warranted (7). In most cases, U.S. MEC follows the WHO guidance updates,

# BOX 2. Conditions associated with increased risk for adverse health events as a result of pregnancy\*

Breast cancer

Complicated valvular heart disease

Cystic fibrosis

Diabetes: insulin dependent; with nephropathy,

retinopathy, or neuropathy or other vascular disease;

or of >20 years' duration

Endometrial or ovarian cancer

**Epilepsy** 

Hypertension (systolic ≥160 mm Hg or diastolic ≥100 mm Hg)

History of bariatric surgery within the past 2 years

HIV: not clinically well or not receiving antiretroviral therapy

Ischemic heart disease

Gestational trophoblastic disease

Hepatocellular adenoma and malignant liver

tumors (hepatoma)

Peripartum cardiomyopathy

Schistosomiasis with fibrosis of the liver

Severe (decompensated) cirrhosis

Sickle cell disease

Solid organ transplantation within the past 2 years

Systemic lupus erythematosus

Thrombogenic mutations

**Tuberculosis** 

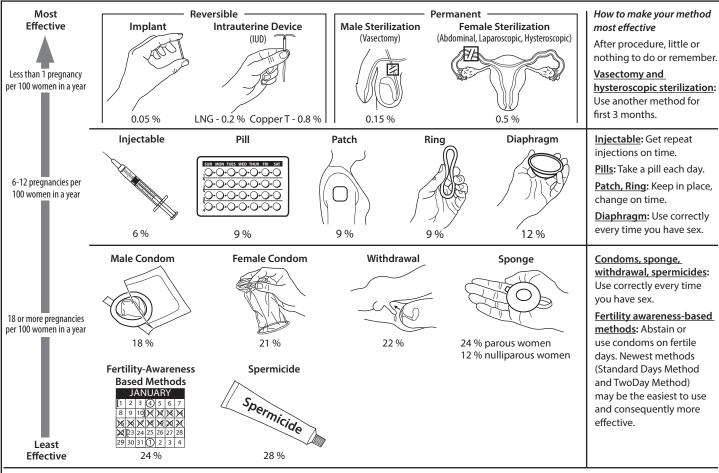
which typically occur every 5 years (or sooner if warranted by new data). However, CDC will review all WHO updates for their application in the United States. CDC also will identify and assess any new literature for the recommendations and medical conditions that are not included in the WHO guidance. CDC will completely review U.S. MEC every 5 years as well. Updates to the guidance will appear on the CDC U.S. MEC website (http://www.cdc.gov/reproductivehealth/UnintendedPregnancy/USMEC.htm).

#### **Acknowledgments**

This report is based, in part, on the work of the Promoting Family Planning Team, Department of Reproductive Health and Research, World Health Organization, and its development of *Medical Eligibility Criteria for Contraceptive Use, 5th edition*.

<sup>\*</sup> Long-acting, highly effective contraceptive methods might be the best choice for women with conditions that are associated with increased risk for adverse health events as a result of pregnancy. These women should be advised that sole use of barrier methods for contraception and behavior-based methods of contraception might not be the most appropriate choice because of their relatively higher typical-use rates of failure.

FIGURE. Effectiveness of family planning methods\*



CONDOMS SHOULD ALWAYS BE USED TO REDUCE THE RISK OF SEXUALLY TRANSMITTED INFECTIONS.

Other Methods of Contraception

Lactational Amenorrhea Method: LAM is a highly effective, temporary method of contraception.

Emergency Contraception: Emergency contraceptive pills or a copper IUD after unprotected intercourse substantially reduces risk of pregnancy.

Sources: Adapted from World Health Organization (WHO) Department of Reproductive Health and Research, Johns Hopkins Bloomberg School of Public Health/Center for Communication Programs (CCP). Knowledge for health project. Family planning: a global handbook for providers (2011 update). Baltimore, MD; Geneva, Switzerland: CCP and WHO; 2011; and Trussell J. Contraceptive failure in the United States. Contraception 2011;83:397–404.

\* The percentages indicate the number out of every 100 women who experienced an unintended pregnancy within the first year of typical use of each contraceptive method.

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#### Conflicts of Interest for Invited Meeting Participants, August 26–28, 2015, Atlanta, Georgia

Rebecca Allen, Nexplanon trainer for Merck and Liletta trainer for Actavis, consultant, advisory board and education grant from Bayer; Mitchell D. Creinin, Nexplanon trainer for Merck, litigation consultant for Bayer, advisory board for Merck and Teva Pharmaceutical Industries, Ltd., consultant for Lemonaid - PolkaDoc app, research support to University of California, Davis from Medicines360, Contramed, Merck, Eunice Kennedy Shriver National Institute of Child Health and Human Development, and Society of Family Planning; Linda Dominguez, speaker for Bayer, Merck, and Actavis; Alison Edelman, royalties from Up to Date, Inc., consultant for Genzyme, grant support from the National Institutes of Health and the Gates Foundation, travel funds from the World Health Organization, grant support and honorarium from Society of Family Planning, honorarium and travel funds from Contemporary Forum, trainer for Merck, consultant for Gynuity Health Projects, honorarium from CDC, Projects In Knowledge, and American Congress of Obstetricians and Gynecologists, advisory board for Agile Therapeutics; Eve Espey, travel funds from the American Congress of Obstetricians and Gynecologists, Society for Family Planning, and U.S. Food and Drug Administration, Reproductive and Drug Advisory Committee for U.S. Food and Drug Administration, travel funds and honoraria from Wayne State University, Telluride Conference, New Mexico Department of Health Clinician Conference, Planned Parenthood National Medical Conference and Society of Family Planning, British Columbia Contraception Access Research Team Conference, and American Congress of Obstetricians and Gynecologists annual meeting; Emily Godfrey, research funding from Bayer Women's Health, Prima-Temp, and Teva Pharmaceutical Industries, Ltd., trainer for Merck and Upstream USA, grant reviewer for Fellowship of Family Planning and Society of Family Planning Research Fund; Mark Hathaway, Liletta trainer and speaker for Actavis and Medicines 360, Nexplanon trainer for Merck, advisory board for Contramed and Afaxys Pharmaceuticals; Paula Hillard, consultant for American Civil Liberties Union, Advanced Health Media, CMEology, National Sleep Foundation, and Planned Parenthood Federation of America, honoraria from National Sleep Foundation, Dignity Health, CMEology, Advance Health Media, and Medscape, editorial board for Advanstar-Contemporary OB/GYN, board examiner for the American Board of Obstetrics and Gynecology, contract reviewer for the U.S. Department of Health and Human Services, editorial board for EBSCO-PEMSoft, Nexplanon trainer for Merck, scientific advisor to Proctor and Gamble, publication royalties from Wiley Blackwell Publishing; Andrew Kaunitz, advisory board participant of Allergan, Bayer, Merck, and Pfizer, clinical trial funding to University of Florida from Agile Therapeutics, Bayer, Merck; Mark Mirochnick, data and safety monitoring board for Merck and ViiV Healthcare, advisory board for Merck; Jeffrey Peipert, research funding from Bayer and Teva Pharmaceutical Industries, Ltd., advisory board for Perrigo; Michael Policar, litigation consultant for Bayer; James Trussell, advisory board for Merck and Teva Pharmaceutical Industries, Ltd., consultant for Bayer; Nanette Wenger, research grants from Alnylam Pharmaceuticals, Gilead Sciences, National Heart, Lung, and Blood Institute, Pfizer, and Society for Women's Health Research, consultant for Amgen, AstraZeneca, Gilead Sciences and Merck; Carolyn Westhoff, data and safety monitoring board for Merck and Bayer, advisory board for Agile Therapeutics, MicroChips Biotech, and Actavis, research support to Columbia University from Medicines360, León Farma, and ContraMed.

#### **Handling Conflicts of Interest**

To promote transparency, all participants were asked to disclose any potential conflicts of interest to CDC prior to the expert meeting and to report any potential conflicts of interest during the introductory portion of the expert meeting. All potential conflicts of interest are listed above. No participants were excluded from discussion based on potential conflicts of interest. CDC staff who ultimately decided and developed these recommendations have no financial interests or other relationships with the manufacturers of commercial products, suppliers of commercial services, or commercial supporters relevant to these recommendations.

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### **Abbreviations and Acronyms**

ARV = antiretroviral [therapy]

BMD = bone mineral density

BMI = body mass index

CHC = combined hormonal contraceptive

COC = combined oral contraceptive

Cu-IUD = copper-containing intrauterine device

DMPA = depot medroxyprogesterone acetate

DVT = deep venous thrombosis

ECP = emergency contraceptive pills

FAB = fertility awareness-based [methods]

hCG = human chorionic gonadotropin

HDL = high-density lipoprotein

HIV = human immunodeficiency virus

IBD = inflammatory bowel disease

IUD = intrauterine device

LARC = long-acting reversible contraception

LDL = low-density lipoprotein

LNG = levonorgestrel

LNG-IUD = levonorgestrel-releasing intrauterine device

NET-EN = norethisterone enantate

NNRTI = nonnucleoside reverse transcriptase inhibitor

NRTI = nucleoside reverse transcriptase inhibitor

PE = pulmonary embolism

PID = pelvic inflammatory disease

POC = progestin-only contraceptive

POP = progestin-only pill

SLE = systemic lupus erythematosus

SSRI = selective serotonin reuptake inhibitors

STD = sexually transmitted disease

UPA = ulipristal acetate

U.S. MEC = U.S. Medical Eligibility Criteria for Contraceptive Use

U.S. SPR = U.S. Selected Practice Recommendations for Contraceptive Use

VTE = venous thromboembolism

#### **Appendix A**

#### Summary of Changes from U.S. Medical Eligibility Criteria for Contraceptive Use, 2010

The classification additions, deletions, and modifications from the 2010 *U.S. Medical Eligibility Criteria for Contraceptive Use* (U.S. MEC) are summarized in the following tables (Box A1) (Tables A1 and A2). For conditions for which classifications changed for one or more contraceptive methods or the condition description underwent a major modification, the changes or modifications are in bold italics (Tables A1 and A2). Conditions that do not appear in this table remain unchanged from the 2010 U.S. MEC.

# BOX A1. Categories for classifying intrauterine devices and hormonal contraceptives

- 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.

TABLE A1. Summary of changes in classifications from U.S. Medical Eligibility Criteria for Contraceptive Use, 2010\*

Condition	Cu-IUD	LNG-IUD	Implants	DMPA	POP	CHCs	Clarification
Breastfeeding a. <21 days postpartum	_	_	2	2	2	4	Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (1).
b. 21 to <30 days postpartum							
i. With other risk factors for VTE (e.g., age ≥35 years, previous VTE, thrombophilia, immobility, transfusion at delivery, peripartum cardiomyopathy, BMI ≥30 kg/ m², postpartum hemorrhage,	_	_	2	2	2	3	Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (1).  CHCs: For women with other risk factors for VTE, these risk
postcesarean delivery, preeclampsia, or smoking)							factors might increase the classification to a category 4.
ii. Without other risk factors for VTE	_	_	2	2	2	3	Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (1).
c. 30–42 days postpartum							
i. With other risk factors for VTE (e.g., age ≥35 years, previous VTE, thrombophilia, immobility, transfusion at delivery, peripartum cardiomyopathy, BMI ≥30 kg/	_	_	1	1	1	3	Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (1).
m <sup>2</sup> , postpartum hemorrhage, postcesarean delivery, preeclampsia, or smoking)							CHCs: For women with other risk factors for VTE, these risk factors might increase the classification to a category 4.
ii. Without other risk factors for VTE	_	_	1	1	1	2	Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (1).
d. >42 days postpartum	_	_	1	1	1	2	Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (1).

TABLE A1. (Continued) Summary of changes in classifications from U.S. Medical Eligibility Criteria for Contraceptive Use, 2010\*

Condition	Cu-IUD	LNG-IUD	Implants	DMPA	POP	CHCs	Clarification
Postpartum (nonbreastfeeding women)							
a. <21 days postpartum	_	_	1	1	1	4	_
b. 21–42 days postpartum							
i. With other risk factors for VTE (e.g., age ≥35 years, previous VTE, thrombophilia, immobility, transfusion at delivery, peripartum cardiomyopathy, BMI ≥30 kg/m², postpartum hemorrhage, postcesarean delivery, preeclampsia, or smoking)	_	_	1	1	1	3	CHCs: For women with other risk factors for VTE, these risk factors might increase the classification to a category 4.
ii. Without other risk factors	_	_	1	1	1	2	_
for VTE c. >42 days postpartum	_	_	1	1	1	1	_
Postpartum (including cesarean delivery)							
a. <10 minutes after delivery of the placenta							IUDs: Insertion of IUDs among postpartum women is safe and does not appear to increase health risks associated
i. Breastfeeding	1	2	_	_	_	_	with IUD use such as infection. Higher rates of expulsion
ii. Nonbreastfeeding	1	1	_	_	_	_	during the postpartum period should be considered as they relate to effectiveness, along with patient access to interval placement (i.e., not related to pregnancy) when expulsion rates are lower.  Breastfeeding: Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (1).
b. 10 minutes after delivery of the placenta to <4 weeks (breastfeeding or nonbreastfeeding)	2	2	_	_	_	_	IUDs: Insertion of IUDs among postpartum women is safe and does not appear to increase health risks associated with IUD use such as infection. Higher rates of expulsion during the postpartum period should be considered as they relate to effectiveness, along with patient access to interval placement (i.e., not related to pregnancy) when expulsion rates are lower.
							Breastfeeding: Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (1).
c. ≥4 weeks (breastfeeding or nonbreastfeeding)	1	1	_	_	_	_	IUDs: Insertion of IUDs among postpartum women is safe and does not appear to increase health risks associated with IUD use such as infection. Higher rates of expulsion during the postpartum period should be considered as they relate to effectiveness, along with patient access to interval placement (i.e., not related to pregnancy) when expulsion rates are lower.
							Breastfeeding: Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (1).
d. Postpartum sepsis	4	4	_	_	_	_	_

TABLE A1. (Continued) Summary of changes in classifications from U.S. Medical Eligibility Criteria for Contraceptive Use, 2010\*

Condition	Cu-IUD	LNG-IUD	Implants	DMPA	POP	CHCs	Clarification
Multiple risk factors for atherosclerotic cardiovascular disease (e.g., older age, smoking, diabetes, hyperten- sion, low HDL, high LDL, or high triglyceride levels)	1	2	2	3	2	3/4	Implants, DMPA, POP: When multiple major risk factors exist, risk for cardiovascular disease might increase substantially. Certain POCs might increase the risk for thrombosis, although this increase is substantially less than with COCs. The effects of DMPA might persist for some time after discontinuation.
							CHCs: When a woman has multiple major risk factors, any of which alone would substantially increase her risk for cardiovascular disease, use of CHCs might increase her risk to an unacceptable level. However, a simple addition of categories for multiple risk factors is not intended; for example, a combination of two category 2 risk factors might not necessarily warrant a higher category.
							Implants, DMPA, POP, CHCs: The recommendations apply to known preexisting medical conditions or characteristics. Few if any screening tests are needed before initiation of contraception. See the U.S. Selected Practice Recommendations for Contraceptive Use (http://www.cdc.gov/reproductivehealth/unintendedpregnancy/usspr.htm)
Superficial venous disorders							
a. Varicose veins	1	1	1	1	1	1	
b. Superficial venous thrombosis (acute or history) Headaches	1	1	1	1	1	3	CHCs: Superficial venous thrombosis might be associated with an increased risk for VTE. If a woman has risk factors for concurrent DVT (e.g., known thrombophilia or cancer) or has current or history of DVT, see recommendations for DVT/PE. Superficial venous thrombosis associated with a peripheral intravenous catheter is less likely to be associated with additional thrombosis and use of CHCs may be considered.
a. Nonmigraine (mild or severe)	1	1	1	1	1	1	CHCs: Classification depends on accurate diagnosis of those severe headaches that are migraines and those headaches that are not, as well as diagnosis of ever experiencing aura. Aura is a specific focal neurologic symptom. For more information about headache classification see <i>The International Headache Classification</i> , 3rd edition (http://www.ihs-classification.org/_downloads/mixed/International-Headache-Classification-III-CHD-III-2013-Beta.pdf). Any new headaches or marked changes in headaches should be evaluated.
<ul> <li>b. Migraine</li> <li>i. Without aura (This category of migraine includes</li> </ul>	1	1	1	1	1	2	CHCs: Classification depends on accurate diagnosis of those severe headaches that are migraines and those headaches that are not, as well as diagnosis of ever experiencing aura.
menstrual migraine.) ii. With aura	1	1	1	1	1	4	Aura is a specific focal neurologic symptom. For more information about headache classification see <i>The International Headache Society Classification, 3rd edition</i> (http://www.ihs-classification.org/_downloads/mixed/International-Headache-Classification-III-ICHD-III-2013-Beta.pdf). Any new headaches or marked changes in headaches should be evaluated. CHCs: Classification is for women without any other risk factors for stroke (e.g., age, hypertension, and smoking).
Multiple sclerosis							
a. With prolonged immobility	1	1	1	2	1	3	_
b. Without prolonged immobility	1	1	1	2	1	1	_
Gestational trophoblastic disease This condition is associated with increased risk for adverse health events as a result of pregnancy							For all subconditions of gestational trophoblastic disease, classifications are based on the assumption that women are under close medical supervision because of the need for monitoring of $\beta$ -hCG levels for appropriate disease surveillance.
(Box 2).  a. Suspected gestational trophoblastic disease (immediate postevacuation)							For all subconditions of gestational trophoblastic disease, classifications are based on the assumption that women are under close medical supervision because of
i. Uterine size first trimester	1	1	1	1	1	1	the need for monitoring of $\beta$ -hCG levels for appropriate
ii. Uterine size second trimester	2	2	1	1	1	1	disease surveillance.

TABLE A1. (Continued) Summary of changes in classifications from U.S. Medical Eligibility Criteria for Contraceptive Use, 2010\*

Condition	C	u-IUD	LN	IG-IUD	Implant	s DMPA	POP	CHCs	Clarification
b. Confirmed gestational trophoblastic disease (after initial evacuation and during monitoring)	Initiation	Continuation	Initiation	Continuation					
i. Undetectable/nonpregnant β-hCG levels	1	1	1	1	1	1	1	1	For all subconditions of gestational trophoblastic disease, classifications are based on the assumption that women are under close medical supervision because of the need for monitoring of $\beta$ -hCG levels for appropriate disease surveillance.
ii. Decreasing β-hCG levels	2	1	2	1	1	1	1	1	For all subconditions of gestational trophoblastic disease, classifications are based on the assumption that women are under close medical supervision because of the need for monitoring of $\beta$ -hCG levels for appropriate disease surveillance.
									IUD: For women at higher risk for disease progression, the benefits of effective contraception must be weighed agains the potential need for early IUD removal.
iii. Persistently elevated β-hCG levels or malignant disease, with no evidence or suspicion of intrauterine disease	2	1	2	1	1	1	1	1	For all subconditions of gestational trophoblastic disease, classifications are based on the assumption that women are under close medical supervision because of the need for monitoring of $\beta$ -hCG levels for appropriate disease surveillance.
iv. Persistently elevated β-hCG levels or malignant disease, with evidence or suspicion of intrauterine disease	4	2	4	2	1	1	1	1	For all subconditions of gestational trophoblastic disease, classifications are based on the assumption that women are under close medical supervision because of the need for monitoring of $\beta$ -hCG levels for appropriate disease surveillance.
Sexually transmitted diseases	Initiation	Continuation	Initiation	Continuation					
a. Current purulent cervicitis or chlamydial infection or gonococcal infection	4	2	4	2	1	1	1	1	IUD continuation: Treat the STD using appropriate antibiotics. The IUD usually does not need to be removed if the woman wants to continue using it. Continued use of an IUD depends on the woman's informed choice and her current risk factors for STDs and PID.
b. Vaginitis (including Trichomonas vaginalis and bacterial vaginosis)	2	2	2	2	1	1	1	1	_
c. Other factors related to STDs	2	2	2	2	1	1	1	1	IUD initiation: Most women do not require additional STD screening at the time of IUD insertion. If a woman with risk factors for STDs has not been screened for gonorrhea and chlamydia according to CDC STD treatment guidelines (2), screening may be performed at the time of IUD insertion and insertion should not be delayed.
High risk for HIV	Initiation 2	Continuation 2	Initiation 2	Continuation 2	1	1	1	1	DMPA: Some studies suggest that women using progestin-only injectable contraception might be at increased risk for HIV acquisition; other studies do not show this association. CDC reviewed all available evidence and agreed that the data were not sufficiently conclusive to change current guidance. However, because of the inconclusive nature of the body of evidence on possible increased risk for HIV acquisition, women using progestin-only injectable contraception should be strongly advised to also always use condoms (male or female) and take other HIV preventive measures. Expansion of contraceptive method mix and further research on the relationship between hormonal contraception and HIV infection are essential. These recommendations will be continually reviewed in light of new evidence.
HIV infection  For women with HIV infection  who are not clinically well or not  receiving ARV therapy, this  condition is associated with  increased risk for adverse health  events as a result of pregnancy	_	_	_	_	1	1	1	1	Implants, DMPA, POP, CHCs: Drug interactions might exist between hormonal contraceptives and ARV drugs; see Drug Interactions section.
(Box 2). a. Clinically well receiving ARV	1	1	1	1	_	_	_	_	_
therapy					_	_	_	_	_
b. Not clinically well or not receiving ARV therapy	2	1	2	1	_	_	_	_	_

TABLE A1. (Continued) Summary of changes in classifications from U.S. Medical Eligibility Criteria for Contraceptive Use, 2010\*

Condition	Cı	u-IUD	LN	IG-IUD	Implants	DMPA	POP	CHCs	Clarification
Cystic fibrosis This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1		1		1 2		1	1	Persons with cystic fibrosis are at increased risk for diabetes, liver disease, gallbladder disease, and VTE (particularly related to use of central venous catheters) and are frequently prescribed antibiotics. Categories assigned to such conditions in U.S. MEC should be the same for women with cystic fibrosis who have these conditions. For cystic fibrosis, classifications are based or the assumption that no other conditions are present; these classifications must be modified in the presence of such conditions.
									Implants, DMPA, POP, CHCs: Certain drugs to treat cystic fibrosis (e.g., lumacaftor) might reduce effectiveness of hormonal contraceptives, including oral, injectable, transdermal, and implantable contraceptives.
Antiretroviral therapy	Initiation	Continuation	Initiation	Continuation					IUD: No known interaction exists between ARV therapy and IUD use. However, IUD insertion is classified as category 2 if the woman is not clinically well or not receiving ARV therapy. Otherwise, both insertion and continuation are classified as category 1 (see HIV Infection section).
a. Nucleoside reverse									
transcriptase inhibitors (NRTIs) i. Abacavir (ABC)	1/2	1	1/2	1	1	1	1	1	_
ii. Tenofovir (TDF)	1/2	1	1/2	1	1	1	1	1	_
iii. Zidovudine (AZT)	1/2	1	1/2	1	1	1	1	1	_
iv. Lamivudine (3TC)	1/2	1	1/2	1	1	1	1	1	_
v. Didanosine (DDI)	1/2	1	1/2	1	1	1	1	1	_
• •	1/2	1	1/2	1	1	1	1	1	_
vi. Emtricitabine (FTC) vii. Stavudine (D4T)		1		1	1	1	1	1	_
b. Nonnucleoside reverse transcriptase inhibitors (NNRTIs)	1/2	,	1/2	1	,	,	,	,	_
i. Efavirenz (EFV)	1/2	1	1/2	1	2	1	2	2	Implants, DMPA, POP, CHCs: Evidence suggests drug interactions between efavirenz and certain hormonal contraceptives. These interactions might reduce the effectiveness of the hormonal contraceptive.
ii. Etravirine (ETR)	1/2	1	1/2	1	1	1	1	1	_
iii. Nevirapine (NVP)	1/2	1	1/2	1	1	1	1	1	_
iv. Rilpivirine (RPV)	1/2	1	1/2	1	1	1	1	1	_
c. Ritonavir-boosted protease inhibitors		•	.,_	·					
i. Ritonavir-boosted atazanavir (ATV/r)	1/2	1	1/2	1	2	1	2	2	Implants, DMPA, POP: Theoretically, drug interactions might occur between certain ritonavir-boosted protease inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive. Any potential effect on contraceptive effectiveness is likely to be lower with DMPA than with other POCs because of the higher dose of DMPA.
									CHCs: Theoretically, drug interactions might occur between certain ritonavir-boosted protease inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive.
ii. Ritonavir-boosted darunavir (DRV/r)	1/2	1	1/2	1	2	1	2	2	Implants, DMPA, POP: Theoretically, drug interactions might occur between certain ritonavir-boosted protease inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive. Any potential effect on contraceptive effectiveness is likely to be lower with DMPA than with other POCs because of the higher dose of DMPA.
									CHCs: Theoretically, drug interactions might occur between certain ritonavir-boosted protease inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive.

TABLE A1. (Continued) Summary of changes in classifications from U.S. Medical Eligibility Criteria for Contraceptive Use, 2010\*

ondition	Cu-IUD		LNO	G-IUD	Implants	DMPA	POP	CHCs	Clarification
iii. Ritonavir-boosted fosamprenavir (FPV/r)	1/2	1	1/2	1	2	1	2	2	Implants, DMPA, POP: Theoretically, drug interactions might occur between certain ritonavir-boosted proteas inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive. Any potential effect on contraceptive effectiveness is likely to be lower with DMPA than with other POCs because of the higher dose of DMPA.
									CHCs: Theoretically, drug interactions might occur between certain ritonavir-boosted protease inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive.
iv. Ritonavir-boosted	1/2	1	1/2	1	1	1	1	1	_
lopinavir (LPV/r) v. Ritonavir-boosted saquinavir (SQV/r)	1/2	1	1/2	1	2	1	2	2	Implants, DMPA, POP: Theoretically, drug interactions might occur between certain ritonavir-boosted protea: inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive. Any potential effect on contraceptive effectiveness is likely to be lower with DMPA than with other POCs because of the higher dose of DMPA.
									CHCs: Theoretically, drug interactions might occur between certain ritonavir-boosted protease inhibitors and certain hormonal contraceptives that might reduc the effectiveness of the hormonal contraceptive.
vi. Ritonavir-boosted tipranavir (TPV/r)	1/2	1	1/2	1	2	1	2	2	Implants, DMPA, POP: Theoretically, drug interactions might occur between certain ritonavir-boosted proteat inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive. Any potential effect on contraceptive effectiveness is likely to be lower with DMPA than with other POCs because of the higher dose of DMPA.
									CHCs: Theoretically, drug interactions might occur between certain ritonavir-boosted protease inhibitors and certain hormonal contraceptives that might reduc the effectiveness of the hormonal contraceptive.
d. Protease inhibitors without ritonavir									
i. Atazanavir (ATV)	1/2	1	1/2	1	1	1	1	2	CHCs: Theoretical concern exists that increased levels of ethinyl estradiol because of interactions with ATV miglincrease the risk for adverse events.
ii. Fosamprenavir (FPV)	1/2	1	1/2	1	2	2	2	3	Implants, DMPA, POP: Theoretical concern exists that interactions between FPV and hormonal contraceptive leading to decreased levels of FPV might diminish effectiveness of the antiretroviral drug. The drug interaction likely involves CYP3A4 pathways; POCs have less effect on CYP3A4 enzymes than CHCs.
									CHCs: Concern exists that interactions between FPV and hormonal contraceptives leading to decreased levels of F might diminish effectiveness of the antiretroviral drug.
iii. Indinavir (IDV)	1/2	1	1/2	1	1	1	1	1	_
iv. Nelfinavir (NFV)	1/2	1	1/2	1	2	1	2	2	Implants, DMPA, POP: Theoretically, drug interactions might occur between certain protease inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive. potential effect on contraceptive effectiveness is likely be lower with DMPA than with other POCs because of higher dose of DMPA. Concern exists that interactions between NFV and POCs might decrease NFV levels.
									CHCs: Evidence suggests drug interactions between certain protease inhibitors and certain hormonal contraceptives. These interactions might reduce the effectiveness of the hormonal contraceptive.

TABLE A1. (Continued) Summary of changes in classifications from U.S. Medical Eligibility Criteria for Contraceptive Use, 2010\*

Condition	Cu	-IUD	LNC	-IUD	Implant	s DMPA	POP	CHCs	Clarification
e. CCR5 co-receptor antagonists i. Maraviroc (MVC)	1/2	1	1/2	1	1	1	1	1	_
f. HIV integrase strand transfer inhibitors									
i. Raltegravir (RAL)	1/2	1	1/2	1	1	1	1	1	_
ii. Dolutegravir (DTG)	1/2	1	1/2	1	1	1	1	1	_
iii. Elvitegravir (EVG)	1/2	1	1/2	1	1	1	1	1	_
g. Fusion inhibitors									
i. Enfuvirtide	1/2	1	1/2	1	1	1	1	1	_
Psychotropic medications									
a. SSRIs		1		1	1	1	1	1	_
St. John's wort		1		1	2	1	2	2	_

Abbreviations: ARV = antiretroviral; BMI = body mass index; CHC = combined hormonal contraceptive; COC = combined oral contraceptive; Cu-IUD = copper-containing intrauterine device; DMPA = depot medroxyprogesterone acetate; DVT = deep venous thrombosis; hCG = human chorionic gonadotropin; HDL = high-density lipoprotein; HIV = human immunodeficiency virus; LDL = low-density lipoprotein; LNG-IUD = levonorgestrel-releasing intrauterine device; PE = pulmonary embolism; PID = pelvic inflammatory disease; POC = progestin-only contraceptive; POP = progestin-only pill; SSRI = selective serotonin uptake inhibitor; STD = sexually transmitted disease; VTE = venous thromboembolism.

TABLE A2. Summary of changes for emergency contraception from U.S. Medical Eligibility Criteria for Contraceptive Use, 2010\*

		Catego	ory		_	
Condition	Cu-IUD	UPA	LNG	coc		
Pregnancy	4	NA	NA	NA	IUD: The IUD is not indicated during pregnancy and should not be used because of the risk for serious pelvic infection and septic spontaneous abortion.	
					ECPs: Although this method is not indicated for a woman with a known or suspected pregnancy, no harm to the woman, the course of her pregnancy, or the fetus if ECPs are inadvertently used is known to exist.	
Breastfeeding	1	1	1	1	UPA: Breastfeeding is not recommended for 24 hours after taking UPA because it is excreted in breast milk with highest concentrations in the first 24 hours, and maximum maternal serum levels are reached 1-3 hours after administration. Mean UPA concentrations in breast milk decrease markedly from 0 to 24-48 hours and then slowly decrease over 5 days (3). Breast milk should be expressed and discarded for 24 hours after taking UPA.	
Past ectopic pregnancy	1	1	1	1	_	
<b>History of bariatric surgery</b> This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).						
a. Restrictive procedures: decrease storage capacity of the stomach (vertical banded gastroplasty, laparoscopic adjustable gastric band, or laparoscopic sleeve gastrectomy)	1	1	1	1	_	
b. Malabsorptive procedures: decrease absorption of nutrients and calories by shortening the functional length of the small intestine (Roux-en-Y gastric bypass or biliopancreatic diversion)	1	1	1	1	_	
History of severe cardiovascular disease (ischemic heart disease, cerebrovascular attack, or other thromboembolic conditions) This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1	2	2	2	_	
Rheumatoid arthritis						
a. Receiving immunosuppressive therapy	2	1	1	1	_	
b. Not receiving immunosuppressive therapy	1	1	1	1	_	
Migraine	1	1	1	2	_	
Inflammatory bowel disease (ulcerative colitis or Crohn's disease)	1	1	1	1	_	
Severe liver disease (including jaundice) This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1	2	2	2	_	

<sup>\*</sup>For conditions for which classification changed for one or more contraceptive methods or the condition description underwent a major modification, the changes or modifications are in bold italics.

TABLE A2. (Continued) Summary of changes for emergency contraception from U.S. Medical Eligibility Criteria for Contraceptive Use, 2010\*

		Catego	ory		
Condition	Cu-IUD	UPA	UPA LNG		
Solid organ transplantation This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).					
a. Complicated: graft failure (acute or chronic), rejection, or cardiac allograft vasculopathy	3	1	1	1	_
b. Uncomplicated	2	1	1	1	_
Repeated ECP use	1	1	1	1	<b>ECPs:</b> Recurrent ECP use is an indication that the woman requires further counseling about other contraceptive options. Frequently repeated ECP use might be harmful for women with conditions classified as 2, 3, or 4 for CHC or POC use.
Sexual assault	2	1	1	1	IUD: Women who have experienced sexual assault are at increased risk for STDs. According to CDC STD treatment guidelines, routine presumptive treatment of chlamydia, gonorrhea, and trichomonas is recommended after sexual assault (2). Women with current purulent cervicitis or chlamydial infection or gonococcal infection should not undergo IUD insertion (category 4,
Obesity (BMI ≥30 kg/m²)	1	2	2	2	ECPs: ECPs might be less effective among women with BMI $\ge$ 30 kg/m <sup>2</sup> than among women with BMI < 25 kg/m <sup>2</sup> . Despite this, no safety concerns exist.
CYP3A4 inducers (e.g., bosentan, carbamazepine, felbamate, griseofulvin, oxcarbazepine, phenytoin, rifampin, St. John's wort, topiramate, efavirenz, and lumacaftor)	1	2	2	2	ECPs: Strong CYP3A4 inducers might reduce the effectiveness of ECPs.

Abbreviations: BMI = body mass index; CHC = combined hormonal contraceptive; COC = combined oral contraceptive; Cu-IUD = copper-containing intrauterine device; ECP = emergency contraceptive pill; IUD = intrauterine device; LNG = levonorgestrel; NA = not applicable; POC = progestin-only contraceptive; STD = sexually transmitted disease; UPA = ulipristal acetate.

\* For conditions for which classification changed for one or more contraceptive methods or the condition description underwent a major modification, the changes or modifications are in bold italics.

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#### **Appendix B**

#### **Classifications for Intrauterine Devices**

Classifications for intrauterine devices (IUDs) are for the copper-containing IUD and levonorgestrel-releasing IUD (containing a total of either 13.5 mg or 52 mg levonorgestrel) (Box B1) (Table B1). IUDs do not protect against sexually transmitted diseases (STDs), including human immunodeficiency virus (HIV), and women using these methods should be counseled that consistent and correct use of the male latex condom reduces the risk for transmission of HIV and other STDs. Use of female condoms can provide protection from transmission of STDs, although data are limited.

#### BOX B1. Categories for classifying intrauterine devices

- 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.

TABLE B1. Classifications for intrauterine devices, including the copper-containing intrauterine device and levonorgestrel-releasing intrauterine device

	Cate	egory			
Condition	Cu-IUD	LNG-IUD	Clarifications/Evidence/Comments		
Personal Characteristics and Repro	ductive History				
Pregnancy	4	4	<b>Clarification:</b> The IUD is not indicated during pregnancy and should not be used because of the risk for serious pelvic infection and septic spontaneous abortion.		
Age					
a. Menarche to <20 years	2	2	<b>Comment:</b> Concern exists both about the risk for expulsion from nulliparity and for STDs from sexual behavior in younger age groups.		
b. ≥20 years	1	1			
Parity					
a. Nulliparous	2	2	<b>Evidence:</b> Data conflict about whether IUD use is associated with infertility among nulliparous women, although well-conducted studies suggest no increased risk (1–9).		
b. Parous	1	1	_		
<b>Postpartum</b> (including cesarean delivery)					
a. <10 minutes after delivery of the			Clarification: Insertion of IUDs among postpartum women is safe and does		
placenta i. Breastfeeding	1	2	not appear to increase health risks associated with IUD use such as infection. Higher rates of expulsion during the postpartum period should be considered as they relate to effectiveness, along with patient access to interval placement (i.e., not related to pregnancy) when expulsion rates are lower.		
			Clarification (breastfeeding): Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (10).		
ii. Nonbreastfeeding	1	1	Evidence: Studies suggest that immediate postplacental (<10 minutes) and early postpartum (10 minutes up until 72 hours) placement of Cu-IUDs and LNG-IUDs is associated with increased risk for expulsion compared with interval placement (i.e., not related to pregnancy). Early postpartum placemen has similar or increased risk for expulsion compared with immediate postplacental placement. Although immediate postplacental placement at the time of cesarean delivery might have increased risk for expulsion compared with interval placement, risk appears lower than that for placement at the time of vaginal delivery. Evidence for infection, perforation, and removals for pain o bleeding are limited; however, these events are rare (11–62).		
			Evidence (breastfeeding): Two randomized controlled trials found conflicting results on breastfeeding outcomes when LNG-IUDs were initiated immediately postpartum compared with 6–8 weeks postpartum. Initiation of LNG-IUDs immediately postpartum had no other harmful effect on infant health, growth, or development (63,64). Breastfeeding women using IUDs do not have an increased risk for certain IUD-related adverse events including expulsion, infection, pain, or bleeding compared with nonbreastfeeding women. The risk for perforation is increased independently among breastfeeding women and among women ≤36 weeks postpartum, compared with non-postpartum women; however, the absolute risk for perforation remains low (11–62,65).		
			Comment (breastfeeding): Certain women might be at risk for breastfeedin difficulties, such as women with previous breastfeeding difficulties, certain medical conditions, or certain perinatal complications and those who deliver preterm. For these women, as for all women, discussions about contraception for breastfeeding women should include information about risks, benefits, and alternatives.		

TABLE B1. (Continued) Classifications for intrauterine devices, including the copper-containing intrauterine device and levonorgestrel-releasing intrauterine device

	Cate	egory	
Condition	Cu-IUD	LNG-IUD	Clarifications/Evidence/Comments
b. 10 minutes after delivery of the placenta to <4 weeks (breastfeeding or nonbreastfeeding)	2	2	Clarification: Insertion of IUDs among postpartum women is safe and does not appear to increase health risks associated with IUD use such as infection. Higher rates of expulsion during the postpartum period should be considered as they relate to effectiveness, along with patient access to interval placement (i.e., not related to pregnancy) when expulsion rates are lower.
			Clarification (breastfeeding): Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (10).
			Evidence: Studies suggest that immediate postplacental (<10 minutes) and early postpartum (10 minutes up until 72 hours) placement of Cu-IUDs and LNG-IUDs is associated with increased risk for expulsion compared with interval placement (i.e., not related to pregnancy). Early postpartum placement has similar or increased risk for expulsion compared with immediate postplacental placement. Although immediate postplacental placement at the time of cesarean delivery might have increased risk for expulsion compared with interval placement, risk appears lower than that for placement at the time of vaginal delivery. Evidence for infection, perforation, and removals for pain or bleeding are limited; however, these events are rare (11–62).
			Evidence (breastfeeding): Two randomized controlled trials found conflicting results on breastfeeding outcomes when LNG-IUDs were initiated immediately postpartum compared with 6–8 weeks postpartum. Initiation of LNG-IUDs immediately postpartum had no other harmful effect on infant health, growth, or development (63,64). Breastfeeding women using IUDs do not have an increased risk for certain IUD-related adverse events including expulsion, infection, pain, or bleeding compared with nonbreastfeeding women. The risk for perforation is increased independently among breastfeeding women and among women ≤36 weeks postpartum, compared with non-postpartum women; however, the absolute risk for perforation remains low (11–62,65).
			Comment (breastfeeding): Certain women might be at risk for breastfeeding difficulties, such as women with previous breastfeeding difficulties, certain medical conditions, or certain perinatal complications and those who deliver preterm. For these women, as for all women, discussions about contraception for breastfeeding women should include information about risks, benefits, and alternatives.
c. ≥4 weeks (breastfeeding or nonbreastfeeding)	1	1	Clarification: Insertion of IUDs among postpartum women is safe and does not appear to increase health risks associated with IUD use such as infection. Higher rates of expulsion during the postpartum period should be considered as they relate to effectiveness, along with patient access to interval placement (i.e., not related to pregnancy) when expulsion rates are lower.
			Clarification (breastfeeding): Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (10).
			Evidence (breastfeeding): Initiation of LNG-IUDs at 4 weeks postpartum or later demonstrated no detrimental effect on breastfeeding outcomes and no harmful effect on infant health, growth, or development (63,64). Breastfeeding women using IUDs do not have an increased risk for certain IUD-related adverse events including expulsion, infection, pain, or bleeding compared with nonbreastfeeding women. The risk for perforation is increased independently among breastfeeding women and among women ≤36 weeks postpartum, compared with non-postpartum women; however, the absolute risk for perforation remains low (11–62,65).
			Comment (breastfeeding): Certain women might be at risk for breastfeeding difficulties, such as women with previous breastfeeding difficulties, certain medical conditions, or certain perinatal complications and those who deliver preterm. For these women, as for all women, discussions about contraception for breastfeeding women should include information about risks, benefits, and alternatives.
d. Postpartum sepsis	4	4	Comment: Theoretical concern exists that postpartum insertion of an IUD in a women with recent charjoannianitis or current endometritis might be

 $associated\ with\ increased\ complications.$ 

in a women with recent chorioamnionitis or current endometritis might be

TABLE B1. (Continued) Classifications for intrauterine devices, including the copper-containing intrauterine device and levonorgestrel-releasing intrauterine device

	Cate	egory	
Condition	Cu-IUD	LNG-IUD	Clarifications/Evidence/Comments
Postabortion a. First trimester	1	1	Clarification: IUDs can be inserted immediately after spontaneous or induced abortion.
			Evidence: Risk for complications from immediate versus delayed insertion of an IUD after abortion did not differ. Expulsion was greater when an IUD was inserted after a second trimester abortion than when inserted after a first trimester abortion. Safety or expulsion for postabortion insertion of an LNG-IUD did not differ from that of a Cu-IUD (66).
b. Second trimester c. Immediate postseptic abortion	2 4	2 4	<b>Comment:</b> Insertion of an IUD might substantially worsen the condition.
Past ectopic pregnancy	1	1	Comment: The absolute risk for ectopic pregnancy is extremely low because of the high effectiveness of IUDs. However, when a woman becomes pregnant during IUD use, the relative likelihood of ectopic pregnancy increases substantially.
History of pelvic surgery (see Postpartum [Including Cesarean Delivery] section) Smoking	1	1	_
a. Age <35 years b. Age ≥35 years	1	1	_
i. <15 cigarettes per day ii. ≥15 cigarettes per day	1 1	1 1	_ _
Obesity a. BMI ≥30 kg/m <sup>2</sup> b. Menarche to <18 years and BMI ≥30 kg/m <sup>2</sup>	1 1	1 1	_ _
History of bariatric surgery This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2). a. Restrictive procedures: decrease storage capacity of the stomach (vertical banded gastroplasty, laparoscopic adjustable gastric band, or laparoscopic sleeve gastrectomy)	1	1	_
b. Malabsorptive procedures: decrease absorption of nutrients and calories by shortening the functional length of the small intestine (Roux-en-Y gastric bypass or biliopancreatic diversion)	1	1	_
Cardiovascular Disease Multiple risk factors for atherosclerotic cardiovascular disease (e.g., older age, smoking, diabetes, hypertension, low HDL, high LDL, or high triglyceride levels)	1	2	_
Hypertension Systolic blood pressure ≥160 mm Hg or diastolic blood pressure ≥100 mm Hg are associated with increased risk for adverse health events as a result of pregnancy (Box 2). a. Adequately controlled hypertension	1	1	Clarification: For all categories of hypertension, classifications are based on the assumption that no other risk factors for cardiovascular disease exist. When multiple risk factors do exist, risk for cardiovascular disease might increase substantially. A single reading of blood pressure level is not sufficient to classify a woman as hypertensive.
b. Elevated blood pressure levels (properly taken measurements) i. Systolic 140–159 mm Hg or diastolic 90–99 mm Hg ii. Systolic ≥160 mm Hg or diastolic ≥100 mm Hg	1	1 2	Clarification: For all categories of hypertension, classifications are based on the assumption that no other risk factors for cardiovascular disease exist. When multiple risk factors do exist, risk for cardiovascular disease might increase substantially. A single reading of blood pressure level is not sufficient to classify a woman as hypertensive.  Comment: Theoretical concern exists about the effect of LNG on lipids. Use of Cu-IUDs has no restrictions.

TABLE B1. (Continued) Classifications for intrauterine devices, including the copper-containing intrauterine device and levonorgestrel-releasing intrauterine device

	Cate	egory	
Condition	Cu-IUD	LNG-IUD	Clarifications/Evidence/Comments
c. Vascular disease	1	2	Clarification: For all categories of hypertension, classifications are based on the assumption that no other risk factors for cardiovascular disease exist. When multiple risk factors do exist, risk for cardiovascular disease might increase substantially. A single reading of blood pressure level is not sufficient to classify a woman as hypertensive.
			<b>Comment:</b> Theoretical concern exists about the effect of LNG on lipids. Use of Cu-IUDs has no restrictions
History of high blood pressure during pregnancy (when current blood pressure is measurable and normal) Deep venous thrombosis/ Pulmonary embolism a. History of DVT/PE, not receiving anticoagulant therapy	1	1	_
i. Higher risk for recurrent DVT/PE (one or more risk factors)  • History of estrogen-associated DVT/PE  • Pregnancy-associated DVT/PE  • Idiopathic DVT/PE  • Known thrombophilia, including antiphospholipid syndrome  • Active cancer (metastatic, receiving therapy, or within 6 months after clinical remission), excluding nonmelanoma skin cancer	1	2	
History of recurrent DVT/PE     ii. Lower risk for recurrent DVT/PE	1	2	_
(no risk factors) b. Acute DVT/PE	2	2	<b>Evidence:</b> No direct evidence exists on the use of POCs among women with acute DVT/PE. Although findings on the risk for venous thrombosis with the use of POCs in otherwise healthy women are inconsistent, any small increased risk is substantially less than that with COCs (67–69).
c. DVT/PE and established anticoagulant therapy for at least 3 months			<b>Evidence:</b> No direct evidence exists on the use of POCs among women with acute DVT/PE. Although findings on the risk for venous thrombosis with the use of POCs in otherwise healthy women are inconsistent, any small increased risk is substantially less than that with COCs (67–69).
			<b>Evidence:</b> Limited evidence indicates that insertion of the LNG-IUD does not pose major bleeding risks in women receiving chronic anticoagulant therapy (70–73).
			<b>Comment:</b> The LNG-IUD might be a useful treatment for menorrhagia in women receiving long-term anticoagulation therapy.
i. Higher risk for recurrent DVT/PE (one or more risk factors)  • Known thrombophilia, including antiphospholipid syndrome  • Active cancer (metastatic, receiving therapy, or within 6 months after clinical remission), excluding nonmelanoma skin cancer  • History of recurrent DVT/PE	2	2	_
ii. Lower risk for recurrent DVT/PE (no risk factors)	2	2	_
d. Family history (first-degree relatives)	1	1	_
e. Major surgery	4	•	
i. With prolonged immobilization ii. Without prolonged immobilization	1	2 1	_ _
f. Minor surgery without immobilization	1	1	

TABLE B1. (Continued) Classifications for intrauterine devices, including the copper-containing intrauterine device and levonorgestrel-releasing intrauterine device

Condition  Known thrombogenic mutations (e.g., factor V Leiden; prothrombin mutation; and protein S, protein C, and antithrombin deficiencies) This condition is associated with increased risk for adverse health		Cate	gory		_
	Cı	ı-IUD	L	NG-IUD	Clarifications/Evidence/Comments
		1		2	<b>Clarification:</b> Routine screening is not appropriate because of the rarity of the conditions and the high cost of screening.
events as a result of pregnancy (Box 2). <b>Superficial venous disorders</b>					
a. Varicose veins     b. Superficial venous thrombosis     (acute or history)		1 1		1 1	_ _
Current and history of ischemic heart disease This condition is associated with		1	Initiation 2	Continuation 3	<b>Comment:</b> Theoretical concern exists about the effect of LNG on lipids. Use of Cu-IUDs has no restrictions.
increased risk for adverse health events as a result of pregnancy (Box 2).					
Stroke (history of cerebrovascular accident) This condition is associated with increased risk for adverse health		1		2	<b>Comment:</b> Theoretical concern exists about the effect of LNG on lipids. Use of Cu-IUDs has no restrictions.
events as a result of pregnancy (Box 2). Valvular heart disease Complicated valvular heart disease is a condition associated with increased risk for adverse health events as a result of pregnancy (Box 2).					<b>Comment:</b> According to the American Heart Association, administration of prophylactic antibiotics solely to prevent endocarditis is not recommended for patients who undergo genitourinary tract procedures, including insertion removal of IUDs (74).
a. Uncomplicated b. Complicated (pulmonary hypertension, risk for atrial fibrillation, or history of subacute		1		1	
bacterial endocarditis) Peripartum cardiomyopathy This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).					<b>Evidence:</b> No direct evidence exists on the safety of IUDs among women with peripartum cardiomyopathy. Limited indirect evidence from noncomparative studies did not demonstrate any cases of arrhythmia or infective endocarditis in women with cardiac disease who used IUDs (75).
a. Normal or mildly impaired cardiac function (New York Heart Association Functional Class I or II: patients with no limitation of activities or patients with slight,					<b>Comment:</b> IUD insertion might induce cardiac arrhythmias in healthy women; women with peripartum cardiomyopathy have a high incidence of cardiac arrhythmias.
mild limitation of activity) (76) i. <6 months		2		2	
ii. ≥6 months		2		2	
b. Moderately or severely impaired cardiac function (New York Heart Association Functional Class III or IV: patients with marked limitation of activity or patients who should be at complete rest) (76)		2		2	
Rheumatic Diseases Systemic lupus erythematosus This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	Initiation	Continuation			
a. Positive (or unknown) antiphospholipid antibodies	1	1		3	Clarification: Persons with SLE are at increased risk for ischemic heart disease, stroke, and VTE. Categories assigned to such conditions in U.S. MEC should be the same for women with SLE who have these conditions. For all subconditions of SLE, classifications are based on the assumption that no other risk factors for cardiovascular disease are present; these classifications must be modified in the presence of such risk factors. Many women with SLE can be considered good candidates for most contraceptive methods, including hormonal contraceptives (73,77–94).
					<b>Evidence:</b> Antiphospholipid antibodies are associated with a higher risk for both arterial and venous thrombosis (95,96)

TABLE B1. (Continued) Classifications for intrauterine devices, including the copper-containing intrauterine device and levonorgestrel-releasing intrauterine device

_		Cate	gory	_
Condition	(	Cu-IUD	LNG-IUD	Clarifications/Evidence/Comments
b. Severe thrombocytopenia	3	2	2	Clarification: Persons with SLE are at increased risk for ischemic heart disease, stroke, and VTE. Categories assigned to such conditions in U.S. MEC should be the same for women with SLE who have these conditions. For all subconditions of SLE, classifications are based on the assumption that no other risk factors for cardiovascular disease are present; these classifications must be modified in the presence of such risk factors. Many women with SLE can be considered good candidates for most contraceptive methods, including hormonal contraceptives (73,77–94).
				<b>Clarification:</b> Severe thrombocytopenia increases the risk for bleeding. The category should be assessed according to the severity of thrombocytopenia and its clinical manifestations. In women with very severe thrombocytopenia who are at risk for spontaneous bleeding, consultation with a specialist and certain pretreatments might be warranted.
				<b>Evidence:</b> The LNG-IUD might be a useful treatment for menorrhagia in women with severe thrombocytopenia (73).
c. Immunosuppressive therapy	2	1	2	Clarification: Persons with SLE are at increased risk for ischemic heart disease, stroke, and VTE. Categories assigned to such conditions in U.S. MEC should be the same for women with SLE who have these conditions. For all subconditions of SLE, classifications are based on the assumption that no other risk factors for cardiovascular disease are present; these classifications must be modified in the presence of such risk factors. Many women with SLE can be considered good candidates for most contraceptive methods, including hormonal contraceptives (73,77–94).
d. None of the above	1	1	2	Clarification: Persons with SLE are at increased risk for ischemic heart disease, stroke, and VTE. Categories assigned to such conditions in U.S. MEC should be the same for women with SLE who have these conditions. For all subconditions of SLE, classifications are based on the assumption that no other risk factors for cardiovascular disease are present; these classifications must be modified in the presence of such risk factors. Many women with SLE can be considered good candidates for most contraceptive methods, including hormonal contraceptives (73,77–94).
Rheumatoid arthritis	Initiation	Continuation	Initiation Continuation	· · · · · · · · · · · · · · · · · · ·
a. Receiving immunosuppressive therapy     b. Not receiving immunosuppressive therapy	2	1	2 1	_ _
Neurologic Conditions				
Headaches		1	1	
<ul><li>a. Nonmigraine (mild or severe)</li><li>b. Migraine</li></ul>		'	ı	_
<ul> <li>i. Without aura (This category of migraine includes menstrual migraine.)</li> <li>ii. With aura</li> </ul>		1	1	Evidence: No studies directly examined the risk for stroke among women with migraine using LNG-IUDs (97). Limited evidence demonstrated that women using LNG-IUDs do not have an increased risk for ischemic stroke compared with women not using hormonal contraceptives (98).
				Comment: Menstrual migraine is a subtype of migraine without aura. For more information see <i>The International Headache Society Classification, 3rd edition</i> (http://www.ihs-classification.org/_downloads/mixed/International-Headache-Classification-III-ICHD-III-2013-Beta.pdf).
Epilepsy This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2). Multiple sclerosis		1	1	<u> </u>
a. With prolonged immobility b. Without prolonged immobility		1	1 1	
Depressive Disorders Depressive disorders		1	1	Clarification: If a woman is receiving psychotropic medications or St. John's
				wort, see Drug Interactions section.  Evidence: The frequency of psychiatric hospitalizations for women with bipolar disorder or depression did not significantly differ among women using DMPA, LNG-IUD, Cu-IUD, or sterilization (99).

TABLE B1. (Continued) Classifications for intrauterine devices, including the copper-containing intrauterine device and levonorgestrel-releasing intrauterine device

_		Category		_
Condition	Cu-IUD		LNG-IUD	Clarifications/Evidence/Comments
Reproductive Tract Infections and Vaginal bleeding patterns a. Irregular pattern without heavy	d Disorders	Initiatio 1	on Continuation 1	_
bleeding b. Heavy or prolonged bleeding (includes regular and irregular	2	1	2	<b>Clarification:</b> Unusually heavy bleeding should raise suspicion of a serious underlying condition.
patterns)				Evidence: Evidence from studies examining the treatment effects of the LNG-IUD among women with heavy or prolonged bleeding reported no increase in adverse effects and found the LNG-IUD to be beneficial in treatin menorrhagia (100–107).
Unexplained vaginal bleeding (suspicious for serious condition) before evaluation	Initiation Conf 4	inuation Initiation 2 4	on Continuation 2	Clarification: If pregnancy or an underlying pathological condition (e.g., pelvic malignancy) is suspected, it must be evaluated and the category adjusted after evaluation. The IUD does not need to be removed before evaluation.
Endometriosis	2		1	Evidence: LNG-IUD use among women with endometriosis decreased dysmenorrhea, pelvic pain, and dyspareunia (108–112).
Benign ovarian tumors (including cysts) Severe dysmenorrhea	1 2		1 1	Comment: Dysmenorrhea might intensify with Cu-IUD use. LNG-IUD use has been associated with reduction of dysmenorrhea.
Gestational trophoblastic disease This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).				,
a. Suspected gestational trophoblastic disease (immediate postevacuation) i. Uterine size first trimester	1		1	Clarification: For all subconditions of gestational trophoblastic disease, classifications are based on the assumption that women are under close medical supervision because of the need for monitoring of $\beta$ -hCG levels for appropriate disease surveillance.
ii. Uterine size second trimester	2		2	Evidence: Limited evidence suggests that women using an IUD after uterine evacuation for a molar pregnancy are not at greater risk for postmolar trophoblastic disease than are women using other methods of contraception (113
				Comment: The risk for expulsion immediately postevacuation for gestational trophoblastic disease is unknown. Expulsion is greater after IUD insertion immediately postevacuation for a spontaneous or induced abortion in the second trimester compared with IUD insertion after a first trimester abortion
b. Confirmed gestational trophoblastic disease (after initial evacuation and during monitoring)	Initiation Cont	inuation Initiatio	on Continuation	, , , , , , , , , , , , , , , , , , ,
i. Undetectable/nonpregnant β-hCG levels	1	1 1	1	Clarification: For all subconditions of gestational trophoblastic disease, classifications are based on the assumption that women are under close medical supervision because of the need for monitoring of $\beta$ -hCG levels for appropriate disease surveillance.
				<b>Evidence:</b> Limited evidence suggests that women using an IUD after uterine evacuation for a molar pregnancy are not at greater risk for postmolar trophoblastic disease than are women using other methods of contraception (113
				Comment: Once $\beta$ -hCG levels have decreased to nonpregnant levels, the risk for disease progression is likely to be very low.
ii. Decreasing $\beta$ -hCG levels	2	1 2	1	Clarification: For all subconditions of gestational trophoblastic disease, classifications are based on the assumption that women are under close medical supervision because of the need for monitoring of $\beta$ -hCG levels for appropriate disease surveillance.
				<b>Clarification:</b> For women at higher risk for disease progression, the benefits of effective contraception must be weighed against the potential need for early IUD removal.
				<b>Evidence:</b> Limited evidence suggests that women using an IUD after uterine evacuation for a molar pregnancy are not at greater risk for postmolar trophoblastic disease than are women using other methods of contraception (113

TABLE B1. (Continued) Classifications for intrauterine devices, including the copper-containing intrauterine device and levonorgestrel-releasing intrauterine device

_		Cate	gory		_
Condition	Cu-IUD		LNG-IUD		— Clarifications/Evidence/Comments
iii. Persistently elevated β-hCG levels or malignant disease, with no evidence or suspicion of intrauterine disease	2	1	2	1	Clarification: For all subconditions of gestational trophoblastic disease, classifications are based on the assumption that women are under close medical supervision because of the need for monitoring of β-hCG levels for appropriate disease surveillance.
					<b>Evidence:</b> Limited evidence suggests that women using an IUD after uterine evacuation for a molar pregnancy are not at greater risk for postmolar trophoblastic disease than are women using other methods of contraception (113).
iv. Persistently elevated β-hCG levels or malignant disease, with evidence or suspicion of intrauterine disease	4	2	4	2	Clarification: For all subconditions of gestational trophoblastic disease, classifications are based on the assumption that women are under close medical supervision because of the need for monitoring of $\beta$ -hCG levels for appropriate disease surveillance.
					<b>Evidence:</b> Limited evidence suggests that women using an IUD after uterine evacuation for a molar pregnancy are not at greater risk for postmolar trophoblastic disease than are women using other methods of contraception (113).
					Comment: For women with suspected or confirmed intrauterine disease, an IUD should not be inserted because of theoretical risk for perforation, infection, and hemorrhage. For women who already have an IUD in place, individual circumstance along with the benefits of effective contraception must be weighed against theoretical risks of either removal or continuation of the IUD.
Cervical ectropion		1		1	
Cervical intraepithelial neoplasia		1		2	<b>Comment:</b> Theoretical concern exists that LNG-IUDs might enhance progression of cervical intraepithelial neoplasia.
Cervical cancer (awaiting treatment)	Initiation 4	Continuation 2	Initiation 4	Continuation 2	Comment: Concern exists about the increased risk for infection and bleeding at insertion. The IUD most likely will need to be removed at the time of treatment but until then, the woman is at risk for pregnancy.
Breast disease Breast cancer is associated with increased risk for adverse health events as a result of pregnancy (Box 2).					
a. Undiagnosed mass		1		2	_
b. Benign breast disease		1		1	_
c. Family history of cancer d. Breast cancer		1		1	Comment: Breast cancer is a hormonally sensitive tumor. Concerns about
i. Current		1		4	progression of the disease might be less with LNG-IUDs than with COCs or
ii. Past and no evidence of current		1		3	higher-dose POCs.
disease for 5 years  Endometrial hyperplasia		1		1	Evidence: Among women with endometrial hyperplasia, no adverse health events occurred with LNG-IUD use; most women experienced disease regression (114).
Endometrial cancer This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	Initiation 4	Continuation 2	Initiation 4	Continuation 2	<b>Comment:</b> Concern exists about the increased risk for infection, perforation, and bleeding at insertion. The IUD most likely will need to be removed at the time of treatment, but until then, the woman is at risk for pregnancy.
Ovarian cancer This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).		1		1	<b>Comment:</b> Women with ovarian cancer who undergo fertility-sparing treatment and need contraception may use an IUD.
Uterine fibroids		2		2	Evidence: Among women with uterine fibroids using an LNG-IUD, most experienced improvements in serum levels of hemoglobin, hematocrit, and ferritin and in menstrual blood loss (115). Rates of LNG-IUD expulsion were higher in women with uterine fibroids (11%) than in women without fibroids (0%–3%); these findings were either not statistically significant or significance testing was not conducted (115). Rates of expulsion found in noncomparative studies ranged from 0%–20% (115).  Comment: Women with heavy or prolonged bleeding should be assigned the category for that condition.

TABLE B1. (Continued) Classifications for intrauterine devices, including the copper-containing intrauterine device and levonorgestrel-releasing intrauterine device

		Cate	egory		_
Condition	Cu-IUD 4		LN	IG-IUD	Clarifications/Evidence/Comments
Anatomical abnormalities a. Distorted uterine cavity (any congenital or acquired uterine abnormality distorting the uterine cavity in a manner that is incompatible with IUD insertion)			4		Comment: An anatomical abnormality that distorts the uterine cavity mig preclude proper IUD placement.
b. Other abnormalities (including cervical stenosis or cervical lacerations) not distorting the uterine cavity or interfering with IUD insertion		2		2	_
Pelvic inflammatory disease	Initiation	Continuation	Initiation	Continuation	Comment III Deaders to a total and a CTD and a discussion DID to
a. Past PID	1	1	1	1	Comment: IUDs do not protect against STDs, including HIV, or PID. In women at low risk for STDs, IUD insertion poses little risk for PID.
i. With subsequent pregnancy	1	1	1	1	at low risk for 31Ds, food insertion poses little risk for Pio.
ii. Without subsequent pregnancy	2	2	2	2	
b. Current PID	4	2	4	2	Clarification (continuation): Treat the PID using appropriate antibiotics. The IUD usually does not need to be removed if the woman wants to continue using it. Continued use of an IUD depends on the woman's informed choice and her current risk factors for STDs and PID.
					<b>Evidence:</b> Among IUD users treated for PID, clinical course did not differ regardless of whether the IUD was removed or left in place (116).
Sexually transmitted diseases	Initiation	Continuation	Initiation	Continuation	
a. Current purulent cervicitis or chlamydial infection or gonococcal infection	4	2	4	2	Clarification (continuation): Treat the STD using appropriate antibiotics. The IUD usually does not need to be removed if the woman wants to continue using it. Continued use of an IUD depends on the woman's informed choice and her current risk factors for STDs and PID.
					<b>Evidence:</b> Among women who had an IUD inserted, the absolute risk for subsequent PID was low among women with STD at the time of insertion but greater than among women with no STD at the time of IUD insertion (117–123).
b. Vaginitis (including <i>Trichomonas</i> vaginalis and bacterial vaginosis)	2	2	2	2	_
c. Other factors related to STDs	2	2	2	2	Clarification (initiation): Most women do not require additional STD screening at the time of IUD insertion. If a woman with risk factors for STDs has not been screened for gonorrhea and chlamydia according to CDC STD treatment guidelines (124), screening may be performed at the time of IUD insertion and insertion should not be delayed.
					<b>Evidence:</b> Women who undergo same-day STD screening and IUD insertion have low incidence rates of PID. Algorithms for predicting PID among women with risk factors for STDs have poor predictive value. Risk for PID among women with risk factors for STDs is low (125).
HIV High risk for HIV	Initiation	Continuation	Initiation	Continuation	Evidence: Among women at risk for HIV, Cu-IUD use did not increase risk for
THIGH TISK TOT FILV					HIV acquisition (126–136).
	2	2	2	2	1
HIV infection For women with HIV infection who are not clinically well or not receiving ARV therapy, this condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).					Evidence: Among IUD users, limited evidence shows a low risk for PID among HIV-infected women using IUDs and no higher risk for pelvic infectious complications in HIV-infected than in HIV-noninfected women or among women with varying degrees of HIV severity. IUD use did not adversely affect progression of HIV during 6–45 months of follow-up or when compared with hormonal contraceptive use among HIV-infected women. Furthermore, IUD use among HIV-infected women was not associated with increased risk for
a. Clinically well receiving ARV therapy	1	1	1	1	transmission to sex partners or with increased genital viral shedding (137).
b. Not clinically well or not receiving ARV therapy	2	1	2	1	

TABLE B1. (Continued) Classifications for intrauterine devices, including the copper-containing intrauterine device and levonorgestrel-releasing intrauterine device

		Cate	egory		
Condition	Cu-Il	JD	LI	NG-IUD	Clarifications/Evidence/Comments
Other Infections					
Schistosomiasis Schistosomiasis with fibrosis of the					
liver is associated with increased risk					
for adverse health events as a result					
of pregnancy (Box 2).					
a. Uncomplicated	1			1	_
b. Fibrosis of the liver (if severe, see Cirrhosis section)	1			1	_
Tuberculosis This condition is associated with	Initiation	Continuation	Initiation	Continuation	
increased risk for adverse health					
events as a result of pregnancy (Box 2).  a. Nonpelvic	1	1	1	1	
b. Pelvic	4	3	4	3	Comment: Insertion of an IUD might substantially worsen the condition.
Malaria	1	3	7	1	— —
	•			•	
Endocrine Conditions					
Diabetes Insulin-dependent diabetes; diabetes					
with nephropathy, retinopathy, or					
neuropathy; diabetes with other					
vascular disease; or diabetes of					
>20 years' duration are associated					
with increased risk for adverse health					
events as a result of pregnancy (Box 2).	1			1	
a. History of gestational disease     b. Nonvascular disease	1			1	Evidence: Limited evidence on the use of the LNG-IUD among women with
i. Non-insulin dependent	1			2	insulin-dependent or non-insulin-dependent diabetes suggests that these
ii. Insulin dependent	1			2	methods have little effect on short-term or long-term diabetes control (e.g.,
ii. iiisaiiii aeperiaerit	•			-	glycosylated hemoglobin levels), hemostatic markers, or lipid profile (138,139
c. Nephropathy, retinopathy, or neuropathy	1			2	_
d. Other vascular disease or diabetes	1			2	_
of >20 years' duration					
Thyroid disorders				4	
a. Simple goiter b. Hyperthyroid	1			1	_
c. Hypothyroid	1			1	
,, ,				•	
Gastrointestinal Conditions	1			1	Fulldames Alahassah kura assa yang dan silandah yang silan
Inflammatory bowel disease (ulcerative colitis or Crohn's disease)	1			1	<b>Evidence:</b> Although two case reports described three women with IBD who experienced exacerbation of disease 5 days–25 months after LNG-IUD
					insertion, no comparative studies have examined the safety of IUD use
6 W. I. II					among women with IBD (140).
Gallbladder disease					
a. Symptomatic i. Treated by cholecystectomy	1			2	_
ii. Medically treated	1			2	_
iii. Current	1			2	_
b. Asymptomatic	1			2	_
History of cholestasis					
a. Pregnancy related	1			1	_
b. Past COC related	1			2	Comment: Concern exists that history of COC related cholestasis might
					predict subsequent cholestasis with LNG use. Whether risk exists with use o LNG-IUD is unclear.
Viral hepatitis					
a. Acute or flare	1			1	_
b. Carrier	1			1	_
c. Chronic	1			1	_
Cirrhosis Severe cirrhosis is associated with					
increased risk for adverse health					
events as a result of pregnancy (Box 2).					
	1			1	_
a. Mild (compensated)					

TABLE B1. (Continued) Classifications for intrauterine devices, including the copper-containing intrauterine device and levonorgestrel-releasing intrauterine device

		Cate	egory		_	
Condition	C	u-IUD	LI	NG-IUD	Clarifications/Evidence/Comments	
Liver tumors Hepatocellular adenoma and malignant liver tumors are associated with increased risk for adverse health events as a result of pregnancy (Box 2). a. Benign						
i. Focal nodular hyperplasia		1		2	_	
ii. Hepatocellular adenoma		1		3	Comment: No evidence is available about hormonal contraceptive use in women with hepatocellular adenoma. COC use in healthy women is associated with development and growth of hepatocellular adenoma; whether other hormonal contraceptives have similar effects is not known.	
b. Malignant (hepatoma)		1		3	· —	
Respiratory Conditions Cystic fibrosis This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).		1		1	Clarification: Persons with cystic fibrosis are at increased risk for diabetes, liver disease, gallbladder disease, and VTE (particularly related to use of central venous catheters) and are frequently prescribed antibiotics. Categories assigned to such conditions in U.S. MEC should be the same for women with	
Anemias					cystic fibrosis who have these conditions. For cystic fibrosis, classifications are based on the assumption that no other conditions are present; these classifications must be modified in the presence of such conditions.	
Thalassemia		2		1	Comment: Concern exists about an increased risk for blood loss with Cu-IUDs.	
Sickle cell disease This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).		2	1		Comment: Concern exists about an increased risk for blood loss with Cu-IUDs.	
Iron deficiency anemia		2		1	Comment: Concern exists about an increased risk for blood loss with Cu-IUDs.	
Solid Organ Transplantation Solid organ transplantation This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	Initiation	Continuation	Initiation	Continuation	<b>Evidence:</b> No comparative studies have examined IUD use among transplant patients. Four case reports of transplant patients using IUDs provided inconsistent results, including beneficial effects and contraceptive failures (141).	
a. Complicated: graft failure (acute or chronic), rejection, or cardiac allograft vasculopathy	3	2	3	2		
b. Uncomplicated	2	2	2	2		
Drug Interactions Antiretroviral therapy	Initiation	Continuation	Initiation	Continuation	Clarification: No known interaction exists between ARV therapy and IUD use. However, IUD insertion is classified as category 2 if the woman is not clinically well or not receiving ARV therapy. Otherwise, both insertion and continuation are classified as category 1 (see HIV Infection section).	
a. Nucleoside reverse transcriptase inhibitors (NRTIs)					, (	
i. Abacavir (ABC)	1/2	1	1/2	1	_	
ii. Tenofovir (TDF)	1/2	1	1/2	1	_	
iii. Zidovudine (AZT) iv. Lamivudine (3TC)	1/2 1/2	1 1	1/2 1/2	1 1	_	
v. Didanosine (DDI)	1/2	1	1/2	1	<u> </u>	
vi. Emtricitabine (FTC)	1/2	1	1/2	1		
vii. Stavudine (D4T)	1/2	1	1/2	1		
b. Nonnucleoside reverse transcriptase inhibitors (NNRTIs)	1/2	·	1/2	·		
i. Efavirenz (EFV)	1/2	1	1/2	1	_	
ii. Etravirine (ETR)	1/2	1	1/2	1	_	
iii. Nevirapine (NVP)	1/2	1	1/2	1	_	
iv. Rilpivirine (RPV) c. Ritonavir-boosted protease inhibitors	1/2	1	1/2	1	_	
i. Ritonavir-boosted atazanavir (ATV/r)	1/2	1	1/2	1	_	
ii. Ritonavir-boosted darunavir (DRV/r)	1/2	1	1/2	1		

TABLE B1. (Continued) Classifications for intrauterine devices, including the copper-containing intrauterine device and levonorgestrel-releasing intrauterine device

		Ca	tegory		
Condition		Cu-IUD	L	NG-IUD	Clarifications/Evidence/Comments
iii. Ritonavir-boosted fosamprenavir (FPV/r)	1/2	1	1/2	1	_
iv. Ritonavir-boosted lopinavir (LPV/r)	1/2	1	1/2	1	_
v. Ritonavir-boosted saquinavir (SQV/r)	1/2	1	1/2	1	_
vi. Ritonavir-boosted tipranavir (TPV/r)	1/2	1	1/2	1	_
d. Protease inhibitors without ritonavir					
i. Atazanavir (ATV)	1/2	1	1/2	1	_
ii. Fosamprenavir (FPV)	1/2	1	1/2	1	_
iii. Indinavir (IDV)	1/2	1	1/2	1	_
iv. Nelfinavir (NFV)	1/2	1	1/2	1	_
e. CCR5 co-receptor antagonists					
i. Maraviroc (MVC)	1/2	1	1/2	1	_
f. HIV integrase strand transfer inhibitors					
i. Raltegravir (RAL)	1/2	1	1/2	1	_
ii. Dolutegravir (DTG)	1/2	1	1/2	1	_
iii. Elvitegravir (EVG)	1/2	1	1/2	1	_
g. Fusion inhibitors					
i. Enfuvirtide	1/2	1	1/2	1	_
Anticonvulsant therapy					
a. Certain anticonvulsants     (phenytoin, carbamazepine,     barbiturates, primidone, topiramate,     and oxcarbazepine)		1		1	<b>Evidence:</b> Limited evidence suggests use of certain anticonvulsants does not interfere with the contraceptive effectiveness of the LNG-IUD (142).
b. Lamotrigine		1		1	<b>Evidence:</b> No drug interactions have been reported among women with epilepsy who are receiving lamotrigine and using the LNG-IUD (143).
Antimicrobial therapy					
a. Broad-spectrum antibiotics		1		1	_
b. Antifungals		1		1	_
c. Antiparasitics		1		1	_
d. Rifampin or rifabutin therapy		1		1	<b>Evidence:</b> One cross-sectional survey found that rifabutin had no impact on the effectiveness of the LNG-IUD (142).
Psychotropic medications					Comment: For many common psychotropic agents, limited or no theoretical concern exists for clinically significant drug interactions when co-administered with hormonal contraceptives. However, either no or very limited data exist examining potential interactions for these classes of medications.
a. SSRIs		1		1	<u> </u>
St. John's wort		1		1	_

Abbreviations: ARV = antiretroviral; BMI = body mass index; COC = combined oral contraceptive; Cu-IUD = copper-containing IUD; DVT = deep venous thrombosis; hCG = human chorionic gonadotropin; HDL = high-density lipoprotein; HIV = human immunodeficiency virus; IBD = inflammatory bowel disease; IUD = intrauterine device; LDL = low-density lipoprotein; LNG = levonorgestrel; LNG-IUD = levonorgestrel-releasing IUD; PE = pulmonary embolism; PID = pelvic inflammatory disease; POC = progestin-only contraceptive; SLE = systemic lupus erythematosus; SSRI = selective serotonin reuptake inhibitor; STD = sexually transmitted disease; VTE = venous thromboembolism.

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# **Appendix C**

## **Classifications for Progestin-Only Contraceptives**

Classifications for progestin-only contraceptives (POCs) include those for progestin-only implants, depot medroxyprogesterone acetate (DMPA; 150 mg intramuscularly or 104 mg subcutaneously), and progestin-only pills (POPs) (Box C1) (Table C1). POCs do not protect against sexually transmitted diseases (STDs), including human immunodeficiency virus (HIV), and women using these methods should be counseled that consistent and correct use of the male latex condom reduces the risk for transmission of HIV and other STDs. Use of female condoms can provide protection from transmission of STDs, although data are limited.

## BOX C1. Categories for classifying progestin-only contraceptives

- 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.

TABLE C1. Classifications for progestin-only contraceptives, including implants, depot medroxyprogesterone acetate, and progestin-only pills

		Category		
Condition	Implants	DMPA	POPs	Clarifications/Evidence/Comments
Personal Characteristics and Re	productive History		,	
Pregnancy	NA	NA	NA	Clarification: Use of POCs is not required. No known harm to the woman, the course of her pregnancy, or the fetus occurs if POCs are inadvertently used during pregnancy. However, the relation between DMPA use during pregnancy and its effects on the fetus remains unclear.
Age a. Menarche to <18 years b. 18-45 years c. >45 years	1 1 1	2 1 2	1 1 1	Evidence: Most studies have found that women lose BMD during DMPA use but recover BMD after discontinuation. Limited evidence shows a weak association with fracture. However, one large study suggests that women who choose DMPA might be at higher risk for fracture before initiation (1). It is unclear whether adult women with long durations of DMPA use can regain BMD to baseline levels before entering menopause and whether adolescents can reach peak bone mass after discontinuation of DMPA. The relationship between these changes in BMD during the reproductive years and future fracture risk is unknown. Studies generally find no effect of POCs other than DMPA on BMD (1–48).
a. Nulliparous	1	1	1	_
b. Parous	1	1	1	_
Breastfeeding a. <21 days postpartum	2	2	2	Clarification: Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (49).
				Evidence: Two small, randomized controlled trials found no adverse impact on breastfeeding with initiation of etonogestrel implants within 48 hours postpartum. Other studies found that initiation of POPs, injectables, and implants at ≤6 weeks postpartum compared with nonhormonal use had no detrimental effect on breastfeeding outcomes or infant health, growth, and development in the first year postpartum. In general, these studies are of poor quality, lack standard definitions of breastfeeding or outcome measures, and have not included premature or ill infants (50,51).
				Comment: Certain women might be at risk for breastfeeding difficulties, such as women with previous breastfeeding difficulties, certain medical conditions, and certain perinatal complications and those who deliver preterm. For these women, as for all women, discussions about contraception for breastfeeding women should include information about risks, benefits, and alternatives.

TABLE C1. (Continued) Classifications for progestin-only contraceptives, including implants, depot medroxyprogesterone acetate, and progestin-only pills

		Category		
Condition	Implants	DMPA	POPs	Clarifications/Evidence/Comments
b. 21 to <30 days postpartum i. With other risk factors for VTE (e.g., age ≥35 years, previous VTE, thrombophilia, immobility, transfusion at delivery, peripartum cardiomyopathy, BMI ≥30 kg/	2	2	2	Clarification: Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (49).
m <sup>2</sup> , postpartum hemorrhage, postcesarean delivery, preeclampsia, or smoking) ii. Without other risk factors for VTE	2	2	2	Evidence: Two small, randomized controlled trials found no adverse impact on breastfeeding with initiation of etonogestrel implants within 48 hours postpartum. Other studies found that initiation of POPs, injectables, and implants at ≤6 weeks postpartum compared with nonhormonal use had no detrimental effect on breastfeeding outcomes or infant health, growth, and development in the first year postpartum. In general, these studies are of poor quality, lack standard definitions of breastfeeding or outcome measures, and have not included premature or ill infants (50,51).
c. 30–42 days postpartum i. With other risk factors for VTE (e.g., age ≥35 years, previous VTE, thrombophilia, immobility, transfusion at delivery, peripartum cardiomyopathy, BMI ≥30 kg/	1	1	1	Comment: Certain women might be at risk for breastfeeding difficulties, such as women with previous breastfeeding difficulties, certain medical conditions, and certain perinatal complications and those who deliver preterm. For these women, as for all women, discussions about contraception for breastfeeding women should include information about risks, benefits, and alternatives.  Clarification: Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (49).
m <sup>2</sup> , postpartum hemorrhage, postcesarean delivery, preeclampsia, or smoking) ii. Without other risk factors for VTE	1	1	1	Evidence: Two small, randomized controlled trials found no adverse impact on breastfeeding with initiation of etonogestrel implants within 48 hours postpartum. Other studies found that initiation of POPs, injectables, and implants at ≤6 weeks postpartum compared with nonhormonal use had no detrimental effect on breastfeeding outcomes or infant health, growth, and development in the first year postpartum. In general, these studies are of poor quality, lack standard definitions of breastfeeding or outcome measures, and have not included premature or ill infants (50,51).
				Comment: Certain women might be at risk for breastfeeding difficulties, such as women with previous breastfeeding difficulties, certain medical conditions, and certain perinatal complications and those who deliver preterm. For these women, as for all women, discussions about contraception for breastfeeding women should include information about risks, benefits, and alternatives.
d. >42 days postpartum	1	1	1	Clarification: Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (49).
				Evidence: Overall, studies found that initiation of POPs, injectables, and implants at >6 weeks postpartum compared with nonhormonal use had no detrimental effect on breastfeeding outcomes or infant health, growth, and development in the first year postpartum. In general, these studies are of poor quality, lack standard definitions of breastfeeding or outcome measures, and have not included premature or ill infants (51).
				Comment: Certain women might be at risk for breastfeeding difficulties, such as women with previous breastfeeding difficulties, certain medical conditions, and certain perinatal complications and those who deliver preterm. For these women, as for all women, discussions about contraception for breastfeeding women should include information about risks, benefits, and alternatives.

 $TABLE\ C1.\ (Continued)\ Classifications\ for\ progestin-only\ contrace ptives, including\ implants, depot\ medroxyprogesterone\ acetate,\ and\ progestin-only\ pills$ 

		Category		
Condition	Implants	DMPA	POPs	Clarifications/Evidence/Comments
Postpartum (nonbreastfeeding				
women)				
a. <21 days postpartum	1	1	1	_
<ul><li>b. 21–42 days postpartum</li><li>i. With other risk factors for VTE</li></ul>	1	1	1	
(e.g., age ≥35 years, previous VTE, thrombophilia, immobility, transfusion at delivery, peripartum cardiomyopathy, BMI ≥30 kg/m², postpartum hemorrhage, postcesarean delivery,	1	'	,	
preeclampsia, or smoking)				
ii. Without other risk factors for VTE	1	1	1	_
c. >42 days postpartum	1	1	1	_
Postabortion	_			
a. First trimester	1	1	1	<b>Clarification:</b> POCs may be started immediately postabortion.
				<b>Evidence:</b> Limited evidence suggests that no adverse side effects occur when implants (Norplant) or progestin-only injectables (NET-EN) are initiated after first trimester abortion (52–55).
b. Second trimester	1	1	1	Clarification: POCs may be started immediately postabortion.
c. Immediate postseptic abortion	1	1	1	Clarification: POCs may be started immediately postabortion.
Past ectopic pregnancy	1	1	2	Comment: POP users have a higher absolute rate of ectopic pregnancy than do users of other POCs but still lower than women using no method.
History of pelvic surgery	1	1	1	—
Smoking				
a. Age <35 years b. Age ≥35 years	1	1	1	_
i. <15 cigarettes per day	1	1	1	_
ii. ≥15 cigarettes per day	1	1	1	_
Obesity				_
a. BMI ≥30 kg/m <sup>2</sup>	1	1	1	_
b. Menarche to <18 years and BMI ≥30 kg/m <sup>2</sup>	1	2	1	Evidence: Among adult women, generally no association has been found between baseline weight and weight gain among DMPA users compared with nonusers. Evidence is mixed for adolescent DMPA users, with some studies observing greater weight gain among obese compared with normal weight users but other studies showing no association; methodologic differences across studies might account for the differences in findings. Data on other POC methods and other adverse outcomes including weight gain are limited (56–73).
History of bariatric surgery This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).				
a. Restrictive procedures: decrease storage capacity of the stomach (vertical banded gastroplasty, laparoscopic adjustable gastric band, or laparoscopic sleeve gastrectomy)	1	1	1	<b>Evidence:</b> Limited evidence demonstrated no substantial decrease in effectiveness of oral contraceptives among women who underwent laparoscopic placement of an adjustable gastric band (74).
b. Malabsorptive procedures: decrease absorption of nutrients and calories by shortening the functional length of the small intestine (Roux-en-Y gastric bypass or biliopancreatic diversion)	1	1	3	Evidence: Limited evidence demonstrated no substantial decrease in effectiveness of oral contraceptives among women who underwent a biliopancreatic diversion; however, evidence from pharmacokinetic studies suggested conflicting results regarding oral contraceptive effectiveness among women who underwent a jejunoileal bypass (74).
				Comment: Bariatric surgical procedures involving a malabsorptive component have the potential to decrease oral contraceptive effectiveness, perhaps further decreased by postoperative complications such as long-term diarrhea, vomiting, or both.

TABLE C1. (Continued) Classifications for progestin-only contraceptives, including implants, depot medroxyprogesterone acetate, and progestin-only pills

		Category		
Condition	Implants	DMPA	POPs	Clarifications/Evidence/Comments
Cardiovascular Disease Multiple risk factors for atherosclerotic cardiovascular disease (e.g., older age, smoking, diabetes, hypertension, low HDL, high LDL, or high triglyceride levels)	2	3	2	Clarification: When multiple major risk factors exist, risk for cardiovascular disease might increase substantially. Certain POCs might increase the risk for thrombosis, although this increase is substantially less than with COCs. The effects of DMPA might persist for some time after discontinuation.
				Clarification: The recommendations apply to known preexisting medical conditions or characteristics. Few if any screening tests are needed before initiation of contraception. See the U.S. Selected Practice Recommendations for Contraceptive Use (http://www.cdc.gov/reproductivehealth/unintendedpregnancy/usspr.htm).
Hypertension Systolic blood pressure ≥160 mm Hg or diastolic blood pressure ≥100 mm Hg are associated with increased risk for adverse health events as a result of pregnancy (Box 2).				
a. Adequately controlled hypertension	1	2	1	Clarification: For all categories of hypertension, classifications are based on the assumption that no other risk factors exist for cardiovascular disease. When multiple risk factors do exist, risk for cardiovascular disease might increase substantially. A single reading of blood pressure level is not sufficient to classify a woman as hypertensive.
				Clarification: Women adequately treated for hypertension are at lower risk for acute myocardial infarction and stroke than are untreated women. Although no data exist, POC users with adequately controlled and monitored hypertension should be at lower risk for acute myocardial infarction and stroke than are untreated hypertensive POC users.
b. Elevated blood pressure levels (properly taken measurements) i. Systolic 140–159 mm Hg or diastolic 90–99 mm Hg	1	2	1	Clarification: For all categories of hypertension, classifications are based on the assumption that no other risk factors exist for cardiovascular disease. When multiple risk factors do exist, risk for cardiovascular disease might increase substantially. A single
ii. Systolic ≥160 mm Hg or diastolic ≥100 mm Hg	2	3	2	reading of blood pressure level is not sufficient to classify a woman as hypertensive.
				<b>Evidence:</b> Limited evidence suggests that among women with hypertension, those who used POPs or progestin-only injectables had a small increased risk for cardiovascular events compared with women who did not use these methods (75).
c. Vascular disease	2	3	2	Clarification: For all categories of hypertension, classifications are based on the assumption that no other risk factors exist for cardiovascular disease. When multiple risk factors do exist, risk for cardiovascular disease might increase substantially. A single reading of blood pressure level is not sufficient to classify a woman as hypertensive.
				Comment: Concern exists about hypoestrogenic effects and reduced HDL levels, particularly among users of DMPA. However, little concern exists about these effects with regard to POPs. The effects of DMPA might persist for some time after discontinuation.
History of high blood pressure during pregnancy (when current blood pressure is measurable and normal) Deep venous thrombosis/Pulmonary	1	1	1	_
embolism  a. History of DVT/PE, not receiving anticoagulant therapy				

TABLE C1. (Continued) Classifications for progestin-only contraceptives, including implants, depot medroxyprogesterone acetate, and progestin-only pills

only pills						
	Category					
Condition	Imp	olants	DMPA	P	OPs	- Clarifications/Evidence/Comments
i. Higher risk for recurrent DVT/PE (one or more risk factors)  • History of estrogen-associated DVT/PE  • Pregnancy-associated DVT/PE  • Idiopathic DVT/PE  • Known thrombophilia, including antiphospholipid syndrome  • Active cancer (metastatic, receiving therapy, or within 6 months after clinical remission), excluding nonmelanoma skin cancer  • History of recurrent DVT/PE		2	2		2	_
ii. Lower risk for recurrent DVT/PE		2	2		2	_
(no risk factors) b. Acute DVT/PE		2	2		2	<b>Evidence:</b> No direct evidence exists on use of POCs among women with acute DVT/PE. Although findings on the risk for venous thrombosis with use of POCs in otherwise healthy women is inconsistent, any small increased risk is substantially less than that with COCs (75–77).
c. DVT/PE and established anticoagulant therapy for at least 3 months i. Higher risk for recurrent DVT/PE (one or more risk factors)		2	2		2	<b>Evidence:</b> No direct evidence exists on use of POCs among women with DVT/PE receiving anticoagulant therapy. Although findings on the risk for venous thrombosis with use of POCs is inconsistent in otherwise healthy women, any small increased risk is substantially less than that with COCs (75–77).
Known thrombophilia, including antiphospholipid syndrome     Active cancer (metastatic, receiving therapy, or within 6 months after clinical remission), excluding nonmelanoma skin cancer     History of recurrent DVT/PE						Limited evidence indicates that intramuscular injections of DMPA in women receiving chronic anticoagulation therapy does not pose a significant risk for hematoma at the injection site or increase the risk for heavy or irregular vaginal bleeding (78).
<ul><li>ii. Lower risk for recurrent DVT/PE (no risk factors)</li></ul>		2	2		2	
d. Family history (first-degree relatives)		1	1		1	_
e. Major surgery i. With prolonged immobilization		2	2		2	_
ii. Without prolonged immobilization		1	1		1	_
f. Minor surgery without immobilization		1	1		1	_
Known thrombogenic mutations (e.g., factor V Leiden; prothrombin mutation; and protein S, protein C, and antithrombin deficiencies) This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2). Superficial venous disorders		2	2		2	<b>Clarification:</b> Routine screening is not appropriate because of the rarity of the conditions and the high cost of screening.
a. Varicose veins b. Superficial venous thrombosis		1 1	1 1		1 1	
(acute or history)  Current and history of ischemic	Initiation	Continuation		Initiation	Continuation	Comment: Concern exists about hypoestrogenic effects
heart disease This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	2	3	3	2	3	and reduced HDL levels, particularly among users of DMPA. However, little concern exists about these effects with regard to POPs. The effects of DMPA might persist for some time after discontinuation.
Stroke (history of cerebrovascular accident) This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2). Valvular heart disease Complicated valvular heart disease is associated with increased risk for adverse health events as a result of	Initiation 2	Continuation 3	3	Initiation 2	Continuation 3	Comment: Concern exists about hypoestrogenic effects and reduced HDL levels, particularly among users of DMPA. However, little concern exists about these effects with regard to POPs. The effects of DMPA might persist for some time after discontinuation.
pregnancy (Box 2). a. Uncomplicated		1	1		1	_
•						

TABLE C1. (Continued) Classifications for progestin-only contraceptives, including implants, depot medroxyprogesterone acetate, and progestin-only pills

		Cate	egory		
Condition	Implants	DN	<b>ЛРА</b>	POPs	Clarifications/Evidence/Comments
b. Complicated (pulmonary hypertension, risk for atrial fibrillation, or history of subacute bacterial endocarditis)	1		1	1	_
Peripartum cardiomyopathy This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2). a. Normal or mildly impaired cardiac function (New York Heart Association					<b>Evidence:</b> No direct evidence exists on the safety of POCs among women with peripartum cardiomyopathy. Limited indirect evidence from noncomparative studies of women with cardiac disease demonstrated few cases of hypertension, thromboembolism, and heart failure in women with cardiac disease using POPs and DMPA (79).
Functional Class I or II: patients with no limitation of activities or patients with slight, mild limitation of activity) (80)					Comment: Progestin-only implants might induce cardiac arrhythmias in healthy women; women with peripartum cardiomyopathy have a high incidence of cardiac arrhythmias.
i. <6 months	1		1	1	
ii. ≥6 months	1		1	1	
b. Moderately or severely impaired cardiac function (New York Heart Association Functional Class III or IV: patients with marked limitation of activity or patients who should be at complete rest) (80)	2		2	2	
Rheumatic Diseases Systemic lupus erythematosus This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).		Initiation	Continuation		
a. Positive (or unknown) antiphospholipid antibodies	3	3	3	3	Clarification: Persons with SLE are at increased risk for ischemic heart disease, stroke, and VTE. Categories assigned to such conditions in U.S. MEC should be the same for women with SLE who have these conditions. For all subconditions of SLE, classifications are based on the assumption that no other risk factors for cardiovascular disease are present; these classifications must be modified in the presence of such risk factors. Many women with SLE can be considered good candidates for most contraceptive methods, including hormonal contraceptives (81–99).
					<b>Evidence:</b> Antiphospholipid antibodies are associated with a higher risk for both arterial and venous thrombosis (100,101).
b. Severe thrombocytopenia	2	3	2	2	Clarification: Persons with SLE are at increased risk for ischemic heart disease, stroke, and VTE. Categories assigned to such conditions in U.S. MEC should be the same for women with SLE who have these conditions. For all subconditions of SLE, classifications are based on the assumption that no other risk factors for cardiovascular disease are present; these classifications must be modified in the presence of such risk factors. Many women with SLE can be considered good candidates for most contraceptive methods, including hormonal contraceptives (81–99).
					Comment: Severe thrombocytopenia increases the risk for bleeding. POCs might be useful in treating menorrhagia in women with severe thrombocytopenia. However, given the increased or erratic bleeding that might be seen on initiation of DMPA and its irreversibility for 11–13 weeks after administration, initiation of this method in women with severe thrombocytopenia should be done with caution.
c. Immunosuppressive therapy	2	2	2	2	Clarification: Persons with SLE are at increased risk for ischemic heart disease, stroke, and VTE. Categories assigned to such conditions in U.S. MEC should be the same for women with SLE wh have these conditions. For all subconditions of SLE, classifications are based on the assumption that no other risk factors for cardiovascular disease are present; these classifications must be modified in the presence of such risk factors. Many women with SLE can be considered good candidates for most contraceptive methods, including hormonal contraceptives (81–99).

TABLE C1. (Continued) Classifications for progestin-only contraceptives, including implants, depot medroxyprogesterone acetate, and progestin-only pills

		Category		
Condition	Implants	DMPA	POPs	Clarifications/Evidence/Comments
d. None of the above	2	Initiation Continuation 2 2	2	Clarification: Persons with SLE are at increased risk for ischemic heart disease, stroke, and VTE. Categories assigned to such conditions in U.S. MEC should be the same for women with SLE who have these conditions. For all subconditions of SLE, classifications are based on the assumption that no other risk factors for cardiovascular disease are present; these classifications must be modified in the presence of such risk factors. Many women with SLE can be considered good candidates for most contraceptive methods, including hormonal contraceptives (81–99).
Rheumatoid arthritis a. Receiving immunosuppressive therapy	1	2/3	1	Clarification (DMPA): DMPA use among women receiving long- term corticosteroid therapy with a history of, or with risk factors for, nontraumatic fractures is classified as category 3. Otherwise, DMPA use for women with rheumatoid arthritis is classified as category 2. Evidence: Limited evidence shows no consistent pattern of
				improvement or worsening of rheumatoid arthritis with use of oral contraceptives, progesterone, or estrogen (102).
b. Not receiving immunosuppressive therapy  Neurologic Conditions	1	2	1	<b>Evidence:</b> Limited evidence shows no consistent pattern of improvement or worsening of rheumatoid arthritis with use of oral contraceptives, progesterone, or estrogen (102).
Headaches				
a. Nonmigraine (mild or severe) b. Migraine	1	1	1	Evidence: No studies directly examined the risk for stroke among women with migraine using POCs (103). Limited
i. Without aura (This category of migraine includes menstrual migraine.)	1	1	1	evidence demonstrated that women using POPs, DMPA, or implants do not have an increased risk for ischemic stroke compared with nonusers (104).
ii. With aura	1	1	1	Comment: Menstrual migraine is a subtype of migraine without aura. For more information, see <i>The International Headache Society Classification</i> , <i>3rd edition</i> (http://www.ihs-classification.org/_downloads/mixed/International-Headache-Classification-III-ICHD-III-2013-Beta.pdf).
Epilepsy This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1	1	1	Clarification: If a woman is taking anticonvulsants, see Drug Interactions section. Certain anticonvulsants lower POC effectiveness.
Multiple sclerosis a. With prolonged immobility b. Without prolonged immobility	1 1	2 2	1 1	<b>Evidence:</b> Limited evidence suggests that use of COCs or oral contraceptives (type not specified) among women with multiple sclerosis does not worsen the clinical course of disease (105).
				Comment: Women with multiple sclerosis might have compromised bone health from disease-related disability, immobility, and use of corticosteroids. Use of DMPA, which has been associated with small changes in BMD, might be of concern.
Depressive Disorders Depressive disorders	1	1	1	<b>Clarification:</b> If a woman is taking psychotropic medications or St. John's wort, see Drug Interactions section.
				Evidence: The frequency of psychiatric hospitalizations for women with bipolar disorder or depression did not significantly differ among women using DMPA, LNG-IUD, Cu-IUD, or sterilization (106).
Reproductive Tract Infections and D Vaginal bleeding patterns	isorders			
a. Irregular pattern without heavy bleeding	2	2	2	Comment: Irregular menstrual bleeding patterns are common among healthy women. POC use frequently induces an irregular bleeding pattern. Implant use might induce irregular bleeding patterns, especially during the first 3–6 months, although these patterns might persist longer.
b. Heavy or prolonged bleeding (includes regular and irregular patterns)	2	2	2	<b>Clarification:</b> Unusually heavy bleeding should raise the suspicion of a serious underlying condition.

TABLE C1. (Continued) Classifications for progestin-only contraceptives, including implants, depot medroxyprogesterone acetate, and progestin-only pills

		Category		
Condition	Implants	DMPA	POPs	Clarifications/Evidence/Comments
Unexplained vaginal bleeding (suspicious for serious condition) before evaluation	3	3	2	Clarification: If pregnancy or an underlying pathological condition (e.g., pelvic malignancy) is suspected, it must be evaluated and the category adjusted after evaluation.
				Comment: POCs might cause irregular bleeding patterns, which might mask symptoms of underlying pathologic conditions. The effects of DMPA might persist for some time after discontinuation.
Endometriosis	1	1	1	_
Benign ovarian tumors	1	1	1	_
(including cysts)				
Severe dysmenorrhea	1	1	1	
Gestational trophoblastic disease This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2). a. Suspected gestational trophoblastic disease (immediate				Clarification: For all subconditions of gestational trophoblastic disease, classifications are based on the assumption that women are under close medical supervision because of the need for monitoring of $\beta$ -hCG levels for appropriate disease surveillance.
postevacuation)				
i. Uterine size first trimester	1	1	1	
ii. Uterine size second trimester	1	1	1	
<ul> <li>b. Confirmed gestational trophoblastic disease (after initial evacuation and during monitoring)</li> </ul>				
i. Undetectable/nonpregnant β– hCG levels	1	1	1	
ii. Decreasing β-hCG levels	1	1	1	
iii. Persistently elevated β-hCG levels or malignant disease, with no evidence or suspicion of intrauterine disease	1	1	1	
iv. Persistently elevated β-hCG levels or malignant disease, with evidence or suspicion of intrauterine disease	1	1	1	
Cervical ectropion	1	1	1	_
Cervical intraepithelial neoplasia	2	2	1	Evidence: Among women with persistent human papillomavirus infection, long-term DMPA use (≥5 years) might increase the risk for carcinoma in situ and invasive carcinoma (107).
<b>Cervical cancer</b> (awaiting treatment)	2	2	1	Comment: Theoretical concern exists that POC use might affect prognosis of the existing disease. While awaiting treatment, women may use POCs. In general, treatment of this condition can render a woman sterile.
Breast disease Breast cancer is associated with increased risk for adverse health				
events as a result of pregnancy (Box 2).				
a. Undiagnosed mass	2	2	2	Clarification: Evaluation should be pursued as early as possible.
b. Benign breast disease	1	1	1	_
c. Family history of cancer d. Breast cancer	1	1	1	— Comment: Breast cancer is a hormonally sensitive tumor, and
i. Current	4	4	4	the prognosis for women with current or recent breast cancer
ii. Past and no evidence of current disease for 5 years	3	3	3	might worsen with POC use.
Endometrial hyperplasia	1	1	1	
Endometrial cancer This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1	1	1	<b>Comment:</b> While awaiting treatment, women may use POCs. In general, treatment of this condition renders a woman sterile.
Ovarian cancer This condition is associated with increased risk for adverse health	1	1	1	<b>Comment:</b> While awaiting treatment, women may use POCs. In general, treatment of this condition can render a woman sterile.
events as a result of pregnancy (Box 2). <b>Uterine fibroids</b>	1	1	1	Comment: POCs do not appear to cause growth of uterine fibroids.

 $TABLE\ C1.\ (Continued)\ Classifications\ for\ progestin-only\ contrace ptives, including\ implants, depot\ medroxyprogesterone\ acetate,\ and\ progestin-only\ pills$ 

		Category		
Condition	Implants	DMPA	POPs	Clarifications/Evidence/Comments
Pelvic inflammatory disease			1	Comment: Whether POCs, like COCs, reduce the risk for PID
a. Past PID				among women with STDs is unknown; however, they do not
i. With subsequent pregnancy	1	1	1	protect against HIV or lower genital tract STDs.
ii. Without subsequent pregnancy	1	1	1	
b. Current PID	1	1	1	
Sexually transmitted diseases				
a. Current purulent cervicitis or	1	1	1	_
chlamydial infection or gonococcal infection				
b. Vaginitis (including <i>Trichomonas</i>	1	1	1	_
vaginalis and bacterial vaginosis)	·	·	•	
c. Other factors related to STDs	1	1	1	_
HIV				
High risk for HIV	1	1	1	Clarification (DMPA): Some studies suggest that women using progestin-only injectable contraception might be at increased risk for HIV acquisition; other studies do not show this association. CDC reviewed all available evidence and agreed that the data were not sufficiently conclusive to change current guidance. However, because of the inconclusive nature of the body of evidence on possible increased risk for HIV acquisition, women using progestin-only injectable contraception should be strongly advised to also always use condoms (male or female) and take other HIV preventive measures. Expansion of contraceptive method mix and further research on the relationship between hormonal contraception and HIV infection are essential. These recommendations will be continually reviewed in light of new evidence.  Evidence: Overall, evidence does not support an association between oral contraceptives and risk for HIV acquisition, evidence is inconsistent regarding an association between DMPA and increased risk for HIV acquisition, and no studies have
HIV infection For women with HIV infection who	1	1	1	suggested an increased risk for HIV acquisition with etonogestre implants although data are limited (108).  Clarification: Drug interactions might exist between hormonal contraceptives and ARV drugs; see Drug Interactions section.
are not clinically well or not using ARV therapy, this condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).				Evidence: Overall, evidence does not support an association between POC use and progression of HIV. Limited direct evidence on an association between POC use and transmission of HIV to noninfected partners, as well as studies measuring genital viral shedding as a proxy for infectivity, have had mixed results. Studies measuring whether hormonal contraceptive methods affect plasma HIV viral load generally have found no effect (109–111).
Other Infections				
Schistosomiasis Schistosomiasis with fibrosis of the liver is associated with increased risk for adverse health events as a result of pregnancy (Box 2).				
a. Uncomplicated	1	1	1	<b>Evidence:</b> Among women with uncomplicated schistosomiasis, limited evidence showed that DMPA use had no adverse effects on liver function (112).
b. Fibrosis of the liver (if severe, see Cirrhosis section)	1	1	1	_
<b>Tuberculosis</b> This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).				<b>Clarification:</b> If a woman is taking rifampin, see Drug Interactions section. Rifampin is likely to decrease the effectiveness of some POCs.
a. Nonpelvic	1	1	1	
b. Pelvic	1	1	1	
Malaria	1	1	1	_

TABLE C1. (Continued) Classifications for progestin-only contraceptives, including implants, depot medroxyprogesterone acetate, and progestin-only pills

only pills				
		Category		
Condition	Implants	DMPA	POPs	Clarifications/Evidence/Comments
Endocrine Conditions Diabetes Insulin-dependent diabetes; diabetes with nephropathy, retinopathy, or neuropathy; diabetes with other vascular disease; or diabetes of >20 years' duration are associated with increased risk for adverse health events as a result of pregnancy (Box 2).				
a. History of gestational disease	1	1	1	<b>Evidence:</b> POCs had no adverse effects on serum lipid levels in women with a history of gestational diabetes in two small studies (113,114). Limited evidence is inconsistent about the development of noninsulin-dependent diabetes among users of POCs with a history of gestational diabetes (115–118).
b. Nonvascular disease		•	•	Evidence: Among women with insulin-dependent or non-
i. Non-insulin dependent ii. Insulin dependent	2 2	2 2	2 2	insulin-dependent diabetes, limited evidence on use of POCs (POPs, DMPA, and LNG implant) suggests that these methods have little effect on short-term or long-term diabetes control (e.g., glycosylated hemoglobin levels), hemostatic markers, or lipid profile (119–122).
c. Nephropathy, retinopathy, or neuropathy	2	3	2	Comment: Concern exists about hypoestrogenic effects and reduced HDL levels, particularly among users of DMPA. The effects of DMPA might persist for some time after discontinuation. Some POCs might increase the risk for thrombosis, although this increase is substantially less than with COCs.
d. Other vascular disease or diabetes of >20 years' duration	2	3	2	Comment: Concern exists about hypoestrogenic effects and reduced HDL levels, particularly among users of DMPA. The effects of DMPA might persist for some time after discontinuation. Some POCs might increase the risk for thrombosis, although this increase is substantially less than with COCs.
Thyroid disorders	1	1	1	
a. Simple goiter b. Hyperthyroid	1 1	1 1	1 1	_ _
c. Hypothyroid	1	1	1	_
Gastrointestinal Conditions Inflammatory bowel disease (ulcerative colitis or Crohn's disease)	1	2	2	Evidence: Risk for disease relapse among women with IBD using oral contraceptives (most studies did not specify formulation) did not increase significantly from that for nonusers (123).  Comment: Absorption of POPs among women with IBD might be reduced if the woman has substantial malabsorption caused by severe disease or small bowel surgery.  Women with IBD have a higher prevalence of osteoporosis and osteopenia than the general population. Use of DMPA, which has been associated with small changes in BMD, might be of concern.
Gallbladder disease				been associated with small changes in bivib, might be of concern.
a. Symptomatic	2	3	2	
i. Treated by cholecystectomy ii. Medically treated	2 2	2 2	2	
iii. Current	2	2	2	_
b. Asymptomatic	2	2	2	_
History of cholestasis				
a. Pregnancy related b. Past COC related	1 2	1 2	1 2	Comment: Theoretical concern exists that a history of COC- related cholestasis might predict subsequent cholestasis with POC use. However, this has not been documented.
Viral hepatitis		_	_	
a. Acute or flare	1 1	1	1	_
b. Carrier c. Chronic	1	1	1 1	_ _
Cirrhosis	•	1	ı	_
Severe cirrhosis is associated with increased risk for adverse health events as a result of pregnancy (Box 2).				
a. Mild (compensated)	1	1	1	_
b. Severe (decompensated)	3	3	3	
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TABLE C1. (Continued) Classifications for progestin-only contraceptives, including implants, depot medroxyprogesterone acetate, and progestin-only pills

		Category		
Condition	Implants	DMPA	POPs	Clarifications/Evidence/Comments
Liver tumors Hepatocellular adenoma and malignant liver tumors are associated with increased risk for adverse health events as a result of pregnancy (Box 2). a. Benign				
i. Focal nodular hyperplasia	2	2	2	<b>Evidence:</b> Limited direct evidence suggests that hormonal contraceptive use does not influence either progression or regression of liver lesions among women with focal nodular hyperplasia (124).
ii. Hepatocellular adenoma	3	3	3	Comment: No evidence is available about hormonal contraceptive use among women with hepatocellular adenoma. COC use in healthy women is associated with development and growth of hepatocellular adenoma; whether other hormonal contraceptives have similar effects is not known.
b. Malignant (hepatoma)	3	3	3	· —
Respiratory Conditions Cystic fibrosis This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1	2	1	Clarification: Persons with cystic fibrosis are at increased risk for diabetes, liver disease, gallbladder disease, and VTE (particularly related to use of central venous catheters) and are frequently prescribed antibiotics. Categories assigned to such conditions in U.S. MEC should be the same for women with cystic fibrosis who have these conditions. For cystic fibrosis, classifications are based on the assumption that no other conditions are present; these classifications must be modified in the presence of such conditions.  Clarification: Certain drugs to treat cystic fibrosis (e.g., lumacaftor) might reduce effectiveness of hormonal contraceptives, including oral, injectable, transdermal, and implantable contraceptives.  Evidence: Limited evidence suggests that use of COCs or oral contraceptives (type not specified) among women with cystic fibrosis is not associated with worsening of disease severity. Very limited evidence suggests that cystic fibrosis does not impair the effectiveness of hormonal contraception (125).  Comment: Women with cystic fibrosis have a higher prevalence of osteopenia, osteoporosis, and fragility fractures than the general population. Use of DMPA, which has been associated
Anemias				with small changes in BMD, might be of concern.
Thalassemia	1	1	1	_
Sickle cell disease This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1	1	1	<b>Evidence:</b> Among women with sickle cell disease, POC use did not have adverse effects on hematologic parameters and, in some studies, was beneficial with respect to clinical symptoms (126–133).
Iron deficiency anemia	1	1	1	<b>Comment:</b> Changes in the menstrual pattern associated with POC use have little effect on hemoglobin levels.
Solid Organ Transplantation Solid organ transplantation This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).				
a. Complicated: graft failure (acute or chronic), rejection, or cardiac allograft vasculopathy	2	2	2	_
b. Uncomplicated	2	2	2	_

 $TABLE\ C1.\ (Continued)\ Classifications\ for\ progestin-only\ contrace ptives, including\ implants, depot\ medroxyprogesterone\ acetate,\ and\ progestin-only\ pills$ 

Condition		Category		
	Implants	DMPA	POPs	Clarifications/Evidence/Comments
Drug Interactions Antiretroviral therapy				Comment: These recommendations generally are for ARV agents used alone. However, most women receiving ARV therapy are using multiple drugs in combination. In general, whether interactions between ARVs and hormonal contraceptives differ when ARVs are given alone or in combination is unknown.
a. Nucleoside reverse transcriptase inhibitors (NRTIs)				g
i. Abacavir (ABC) ii. Tenofovir (TDF) iii. Zidovudine (AZT)	1 1 1	1 1 1	1 1 1	<b>Evidence:</b> NRTIs do not appear to have significant risk for interactions with hormonal contraceptive methods (134–139).
iv. Lamivudine (3TC) v. Didanosine (DDI)	1 1	1 1	1 1	
vi. Emtricitabine (FTC) vii. Stavudine (D4T) b. Nonnucleoside reverse transcriptase inhibitors (NNRTIs)	1 1	1 1	1	
i. Efavirenz (EFV)	2	1	2	Clarification: Evidence suggests drug interactions between EFV and certain hormonal contraceptives. These interactions might reduce the effectiveness of the hormonal contraceptive.
ii. Etravirine (ETR)	1	1	1	Evidence: One study found that women using etonogestrel implants with EFV had a higher pregnancy rate than women not using ARVs, although confidence intervals overlapped and absolute pregnancy rates were still lower than for other hormonal methods; another study found that etonogestrel levels were decreased and 5% of women had presumptive ovulation while using etonogestrel implants with EFV (140,141). Three studies of women using LNG implants showed increased pregnancy rates for women using EFV-containing ARV therapy compared with no ARV use, although absolute pregnancy rates were still lower than for other hormonal methods in one study (141–143); another study of LNG implant users found no difference in pregnancy rates with EFV compared with no EFV (144).No significant effects were found on pregnancy rates, DMPA levels, EFV levels, or HIV disease progression in women using DMPA and EFV compared with DMPA alone (141,144–148). No significant effects were found on HIV disease progression in women using LNG implants and EFV compared with no ARVs (143). No data have assessed effectiveness of contraceptive implants during later years of use when progestin concentrations are lower and risk for failure from drug interactions might be greater.
iii. Nevirapine (NVP)	1	1	1	Evidence: Five studies found no significant increase in pregnancy rates among women using implants and NVP compared with implants alone (141–144,149). Four studies found no significant increase in pregnancy rates among women using DMPA or other contraceptive injectables and NVP compared with DMPA or other contraceptive injectables alone (141,144,147,150). One study found no ovulations or changes in DMPA concentrations (145). No effect was found on HIV disease progression with use of NVP and DMPA or LNG implants (143,145,147–149,151). No data have assessed effectiveness of contraceptive implants during later years of use when progestin concentrations are lower and risk for failure from drug
iv. Rilpivirine (RPV)	1	1	1	interactions might be greater.

 $TABLE\ C1.\ (Continued)\ Classifications\ for\ progestin-only\ contrace ptives, including\ implants, depot\ medroxyprogesterone\ acetate,\ and\ progestin-only\ pills$ 

		Category		
Condition	Implants	DMPA	POPs	Clarifications/Evidence/Comments
c. Ritonavir-boosted protease inhibitors				
i. Ritonavir-boosted atazanavir (ATV/r)	2	1	2	Clarification: Theoretically, drug interactions might occur between certain ritonavir-boosted protease inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive. Any potential effect on contraceptive effectiveness is likely to be lower with DMPA than with other POCs because of the higher dose of DMPA.
				<b>Evidence:</b> One pharmacokinetic study demonstrated increased progestin concentrations with use of POPs and ATV/r compared with POPs alone (152).
ii. Ritonavir-boosted darunavir (DRV/r)	2	1	2	Clarification: Theoretically, drug interactions might occur between certain ritonavir-boosted protease inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive. Any potential effect on contraceptive effectiveness is likely to be lower with DMPA than with other POCs because of the higher dose of DMPA.
iii. Ritonavir-boosted fosamprenavir (FPV/r)	2	1	2	Clarification: Theoretically, drug interactions might occur between certain ritonavir-boosted protease inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive. Any potential effect on contraceptive effectiveness is likely to be lower with DMPA than with other POCs because of the higher dose of DMPA.
iv. Ritonavir-boosted lopinavir (LPV/r)	1	1	1	Evidence: One study demonstrated no pregnancies, no ovulations, no change in LPV/r level, and no change in HIV disease progression in women using DMPA (153); another study found a small increase in pregnancy rate in women using DMPA with LPV/r compared with no ARV therapy, however confidence intervals overlapped (141). Two studies found no increased risk for pregnancy in women using implants (141,142). Two studies found contraceptive hormones increased in women using LPV/r with DMPA or etonogestrel implants (140,153).
v. Ritonavir-boosted saquinavir (SQV/r)	2	1	2	Clarification: Theoretically, drug interactions might occur between certain ritonavir-boosted protease inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive. Any potential effect on contraceptive effectiveness is likely to be lower with DMPA than with other POCs because of the higher dose of DMPA.
vi. Ritonavir-boosted tipranavir (TPV/r)	2	1	2	Clarification: Theoretically, drug interactions might occur between certain ritonavir-boosted protease inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive. Any potential effect on contraceptive effectiveness is likely to be lower with DMPA than with other POCs because of the higher dose of DMPA.
d. Protease inhibitors without				-
ritonavir i. Atazanavir (ATV)	1	1	1	Comment: When ATV is administered with Cobicistat, theoretical concern exists for a drug interaction with hormonal contraceptives. Cobicistat is an inhibitor of CYP3A and CYP2D6 and could theoretically increase contraceptive hormone levels. However, its effects on CYP enzymes and drug levels might vary when combined with other ARVs.
ii. Fosamprenavir (FPV)	2	2	2	Clarification: Theoretical concern exists that interactions between FPV and hormonal contraceptives leading to decreased levels of FPV might diminish effectiveness of the ARV drug. The drug interaction likely involves CYP3A4 pathways; POCs have less effect on CYP3A4 enzymes than CHCs.
iii. Indinavir (IDV)	1	1	1	— —

 $TABLE\ C1.\ (Continued)\ Classifications\ for\ progestin-only\ contrace ptives, including\ implants, depot\ medroxyprogesterone\ acetate,\ and\ progestin-only\ pills$ 

		Category		
Condition	Implants	DMPA	POPs	Clarifications/Evidence/Comments
iv. Nelfinavir (NFV)	2	1	2	Clarification: Theoretically, drug interactions might occur between certain protease inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive. Any potential effect on contraceptive effectiveness is likely to be lower with DMPA than with other POCs because of the higher dose of DMPA. Concern exists that interactions between NFV and POCs might decrease NFV levels.
				<b>Evidence:</b> One study found no pregnancies, no ovulations, no change in DMPA concentrations and no change in HIV disease progression with use of DMPA and NFV compared with DMPA alone; NFV concentrations were decreased with concomitant DMPA use (145,147).
e. CCR5 co-receptor antagonists				
i. Maraviroc (MVC) f. HIV integrase strand transfer inhibitors	1	1	1	
i. Raltegravir (RAL)	1	1	1	_
ii. Dolutegravir (DTG)	1	1	1	_
iii. Elvitegravir (EVG)	1	1	1	Comment: When EVG is administered with Cobicistat, theoretical concern exists for a drug interaction with hormonal contraceptives. Cobicistat is an inhibitor of CYP3A and CYP2D6 and could theoretically increase contraceptive hormone levels. However, its effects on CYP enzymes and drug levels may vary when combined with other ARVs.
g. Fusion inhibitors				
i. Enfuvirtide	1	1	1	_
Anticonvulsant therapy	•			——————————————————————————————————————
a. Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, and oxcarbazepine)	2	1	3	Clarification: Although the interaction of certain anticonvulsants with POPs and etonogestrel implants is not harmful to women, it is likely to reduce the effectiveness of POPs and etonogestrel implants. Whether increasing the hormone dose of POPs alleviates this concern remains unclear. Use of other contraceptives should be encouraged for women who are long-term users of any of these drugs. Use of DMPA is a category 1 because its effectiveness is not decreased by use of certain anticonvulsants.
				<b>Evidence:</b> Use of certain anticonvulsants might decrease the effectiveness of POCs (154–156).
b. Lamotrigine	1	1	1	<b>Evidence:</b> No drug interactions have been reported among women with epilepsy receiving lamotrigine and POCs (157).
Antimicrobial therapy				
a. Broad-spectrum antibiotics	1	1	1	_
b. Antifungals	1	1	1	_
c. Antiparasitics d. Rifampin or rifabutin therapy	1 2	1 1	1 3	Clarification: Although the interaction of rifampin or rifabutin with POPs and etonogestrel implants is not harmful to women, it is likely to reduce the effectiveness of POPs and etonogestrel implants. Use of other contraceptives should be encouraged for women who are long-term users of any of these drugs. Use of DMPA is a category 1 because its effectiveness is not decreased by use of rifampin or rifabutin. Whether increasing the hormone

TABLE C1. (Continued) Classifications for progestin-only contraceptives, including implants, depot medroxyprogesterone acetate, and progestin-only pills

	Category			
Condition	Implants	DMPA	POPs	Clarifications/Evidence/Comments
Psychotropic medications				Comment: For many common psychotropic agents, limited or no theoretical concern exits for clinically significant drug interactions when co-administered with hormonal contraceptives. However, either no or very limited data exist examining potential interactions for these classes of medications.
a. SSRIs	1	1	1	Evidence: No evidence specifically examined the use of POCs with SSRIs. Limited clinical and pharmacokinetic data do not demonstrate concern for SSRIs decreasing the effectiveness of oral contraceptives. Limited evidence suggests that for women taking SSRIs, the use of hormonal contraceptives was not associated with differences in effectiveness of the SSRI for treatment or in adverse events when compared with women not taking hormonal contraceptives (158).
				Comment: Drugs that are inhibitors of CYP3A4 or CYP2C9 theoretically have the potential to increase levels of contraceptive steroid, which might increase adverse events. Fluvoxamine is an SSRI known to be a moderate inhibitor of both 3A4 and 2C9; however, no clinical or pharmacokinetic studies were identified to explore potential drug-drug interactions.
St. John's wort	2	1	2	Evidence: No evidence specifically examined the use of POCs with St John's wort. Although clinical data are limited, studies with pharmacokinetic and pharmacodynamics outcomes raise concern that St. John's wort might decrease effectiveness of hormonal contraceptives, including increased risk for breakthrough bleeding and ovulation and increased metabolism of estrogen and progestin. Any interactions might be dependent on the dose of St John's wort, and the concentration of active ingredients across types of St. John's wort preparations may vary (159).
				<b>Comment:</b> Any potential effect on contraceptive effectiveness is likely to be lower with DMPA than with other POCs because of the higher dose of DMPA.

Abbreviations: ARV = antiretroviral; BMD = bone mineral density; BMI = body mass index; COC = combined oral contraceptive; DMPA = depot medroxyprogesterone acetate; DVT = deep venous thrombosis; hCG = human chorionic gonadotropin; HDL = high-density lipoprotein; HIV = human immunodeficiency virus; IBD = inflammatory bowel disease; LDL = low-density lipoprotein; LNG = levonorgestrel; NA = not applicable; NET-EN = norethisterone enantate; PE = pulmonary embolism; PID = pelvic inflammatory disease; POC = progestin-only contraceptive; POP = progestin-only pill; SSRI = selective serotonin reuptake inhibitor; STD = sexually transmitted disease; VTE = venous thromboembolism.

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# **Appendix D**

## **Classifications for Combined Hormonal Contraceptives**

Combined hormonal contraceptives (CHCs) include lowdose (containing  $\leq 35 \mu g$  ethinyl estradiol) combined oral contraceptives (COCs), the combined hormonal patch, and the combined vaginal ring (Box D1) (Table D1). Limited information is available about the safety of the combined hormonal patch and combined vaginal ring among women with specific medical conditions. Evidence indicates that the combined hormonal patch and the combined vaginal ring provide comparable safety and pharmacokinetic profiles to COCs with similar hormone formulations (1-33). Pending further studies, the evidence available for recommendations about COCs applies to the recommendations for the combined hormonal patch and vaginal ring. Therefore, the patch and ring should have the same categories as COCs, except where noted. Therefore, the assigned categories should be considered a preliminary best judgement, which will be reevaluated as new data become available.

## BOX D1. Categories for classifying combined hormonal contraceptives

- 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.

COCs, the patch, and the ring do not protect against sexually transmitted diseases (STDs), including human immunodeficiency virus (HIV), and women using these methods should be counseled that consistent and correct use of the male latex condom reduces the risk for transmission of HIV and other STDs. Use of female condoms can provide protection from transmission of STDs, although data are limited

TABLE D1. Classifications for combined hormonal contraceptives, including pill, patch, and ring

Condition	Category CHCs	Clarifications/Evidence/Comments
Personal Characteristics and Reproductive History Pregnancy	NA	<b>Clarification:</b> Use of CHCs is not required. No known harm to the woman, the course of her pregnancy, or the fetus occurs if CHCs are inadvertently used during pregnancy.
Age a. Menarche to <40 years b. ≥40 years	1 2	<b>Evidence:</b> Evidence is inconsistent about whether CHC use affects fracture risk $(34-45)$ , although three recent studies show no effect $(34,35,45)$ . CHC use might decrease BMD in adolescents, especially in those choosing very low-dose formulations (COCs containing $<$ 30 $\mu$ g ethinyl estradiol) $(46-59)$ . CHC use has little to no effect on BMD in premenopausal women $(60-74)$ and might preserve bone mass in those who are perimenopausal $(75-83)$ . BMD is a surrogate marker for fracture risk that might not be valid for premenopausal women and therefore might not accurately predict current or future (postmenopausal) fracture risk $(84-86)$ .
		<b>Comment:</b> The risk for cardiovascular disease increases with age and might increase with CHC use. In the absence of other adverse clinical conditions, CHCs can be used until menopause.
Parity a. Nulliparous	1	_
b. Parous	1	
Breastfeeding a. <21 days postpartum	4	Clarification: Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (87).
		Evidence: Clinical studies demonstrate conflicting results regarding effects on breastfeeding continuation or exclusivity in women exposed to COCs during lactation. No consistent effects on infant growth or illness have been reported. Adverse health outcomes or manifestations of exogenous estrogen in infants exposed to CHCs through breast milk have not been demonstrated; however, studies have been inadequately designed to determine whether a risk for either serious or subtle long-term effects exists (88).
		Evidence: One study examined use of CHCs during the postpartum period and found that VTE rates were higher for CHC users compared with nonusers at all time points postpartum (89). Rates were significantly different only after 13 weeks postpartum; however, the numbers needed to harm were lowest in the first 6 weeks postpartum. VTE risk is increased during pregnancy and the postpartum period; this risk is most pronounced in the first 3 weeks after delivery, decreasing to near baseline levels by 42 days postpartum (90–94).
		Comment: Certain women might be at risk for breastfeeding difficulties, such as women with previous breastfeeding difficulties, certain medical conditions, or certain perinatal complications, and those who deliver preterm. For these women, as for all women, discussions about contraception for breastfeeding women should include information about risks, benefits, and alternatives.
b. 21 to <30 days postpartum i. With other risk factors for VTE (e.g., age ≥35 years, previous VTE, thrombophilia, immobility, transfusion at delivery, peripartum cardiomyopathy, BMI ≥30 kg/m², postpartum hemorrhage, postcesarean delivery, preeclampsia, or smoking)	3	Clarification: Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (87).
		<b>Clarification:</b> For women with other risk factors for VTE, these risk factors might increase the classification to a category 4.
		Evidence: Clinical studies demonstrate conflicting results regarding effects on breastfeeding continuation or exclusivity in women exposed to COCs during lactation. No consistent effects on infant growth or illness have been reported. Adverse health outcomes or manifestations of exogenous estrogen in infants exposed to CHCs through breast milk have not been demonstrated; however, studies have been inadequately designed to determine whether a risk for either serious or subtle long-term effects exists (88).
		Evidence: One study examined use of CHCs during the postpartum period and found that VTE rates were higher for CHC users compared with nonusers at all time points postpartum (80). Pates were significantly different only after 13 weeks

include information about risks, benefits, and alternatives.

near baseline levels by 42 days postpartum (90–94).

points postpartum (89). Rates were significantly different only after 13 weeks postpartum; however, the numbers needed to harm were lowest in the first 6 weeks postpartum. VTE risk is increased during pregnancy and the postpartum period; this risk is most pronounced in the first 3 weeks after delivery, decreasing to

Comment: Certain women might be at risk for breastfeeding difficulties, such as women with previous breastfeeding difficulties, certain medical conditions, or certain perinatal complications, and those who deliver preterm. For these women, as for all women, discussions about contraception for breastfeeding women should

## TABLE D1. (Continued) Classifications for combined hormonal contraceptives, including pill, patch, and ring

#### Condition Category CHCs Clarifications/Evidence/Comments ii. Without other risk factors for VTE Clarification: Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (87). Evidence: Clinical studies demonstrate conflicting results regarding effects on breastfeeding continuation or exclusivity in women exposed to COCs during lactation. No consistent effects on infant growth or illness have been reported. Adverse health outcomes or manifestations of exogenous estrogen in infants exposed to CHCs through breast milk have not been demonstrated; however, studies have been inadequately designed to determine whether a risk for either serious or subtle long-term effects exists (88). Evidence: One study examined use of CHCs during the postpartum period and found that VTE rates were higher for CHC users compared with nonusers at all time points postpartum (89). Rates were significantly different only after 13 weeks postpartum; however, the numbers needed to harm were lowest in the first 6 weeks postpartum. VTE risk is increased during pregnancy and the postpartum period; this risk is most pronounced in the first 3 weeks after delivery, decreasing to near baseline levels by 42 days postpartum (90-94). Comment: Certain women might be at risk for breastfeeding difficulties, such as women with previous breastfeeding difficulties, certain medical conditions, or certain perinatal complications, and those who deliver preterm. For these women as for all women, discussions about contraception for breastfeeding women should include information about risks, benefits, and alternatives. c. 30-42 days postpartum i. With other risk factors for VTE (e.g., age ≥35 years, previous VTE, Clarification: Breastfeeding provides important health benefits for mother and 3 thrombophilia, immobility, transfusion at delivery, peripartum infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months cardiomyopathy, BMI ≥30 kg/m2, postpartum hemorrhage, postcesarean delivery, preeclampsia, or smoking) of life, and continuing breastfeeding through at least 1 year of life as key public health goals (87). Clarification: For women with other risk factors for VTE, these risk factors might increase the classification to a category 4. Evidence: Clinical studies demonstrate conflicting results regarding effects on breastfeeding continuation or exclusivity in women exposed to COCs during lactation. No consistent effects on infant growth or illness have been reported. Adverse health outcomes or manifestations of exogenous estrogen in infants exposed to CHCs through breast milk have not been demonstrated; however, studies have been inadequately designed to determine whether a risk for either serious or subtle long-term effects exists (88). Evidence: One study examined use of CHCs during the postpartum period and found that VTE rates were higher for CHC users compared with nonusers at all time points postpartum (89). Rates were significantly different only after 13 weeks postpartum; however, the numbers needed to harm were lowest in the first 6 weeks postpartum. VTE risk is increased during pregnancy and the postpartum period; this risk is most pronounced in the first 3 weeks after delivery, decreasing to near baseline levels by 42 days postpartum (90-94). Comment: Certain women might be at risk for breastfeeding difficulties, such as women with previous breastfeeding difficulties, certain medical conditions, or certain perinatal complications, and those who deliver preterm. For these women,

See table footnotes on page 69.

as for all women, discussions about contraception for breastfeeding women should

include information about risks, benefits, and alternatives.

TABLE D1. (Continued) Classifications for combined hormonal contraceptives, including pill, patch, and ring

Condition	Category CHCs	Clarifications/Evidence/Comments
ii. Without other risk factors for VTE	2	Clarification: Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (87).
		Evidence: Clinical studies demonstrate conflicting results regarding effects on breastfeeding continuation or exclusivity in women exposed to COCs during lactation. No consistent effects on infant growth or illness have been reported. Adverse health outcomes or manifestations of exogenous estrogen in infants exposed to CHCs through breast milk have not been demonstrated; however, studies have been inadequately designed to determine whether a risk for either serious or subtle long-term effects exists (88).
		Evidence: One study examined use of CHCs during the postpartum period and found that VTE rates were higher for CHC users compared with nonusers at all time points postpartum (89). Rates were significantly different only after 13 weeks postpartum; however, the numbers needed to harm were lowest in the first 6 weeks postpartum. VTE risk is increased during pregnancy and the postpartum period; this risk is most pronounced in the first 3 weeks after delivery, decreasing to near baseline levels by 42 days postpartum (90–94).
		Comment: Certain women might be at risk for breastfeeding difficulties, such as women with previous breastfeeding difficulties, certain medical conditions, or certain perinatal complications, and those who deliver preterm. For these women, as for all women, discussions about contraception for breastfeeding women should include information about risks, benefits, and alternatives.
d. >42 days postpartum	2	Clarification: Breastfeeding provides important health benefits for mother and infant. The U.S. Department of Health and Human Services recommends increasing the proportion of infants initially breastfed, exclusively breastfed through 6 months of life, and continuing breastfeeding through at least 1 year of life as key public health goals (87).
		Evidence: Clinical studies demonstrate conflicting results regarding effects on breastfeeding continuation or exclusivity in women exposed to COCs during lactation. No consistent effects on infant growth or illness have been reported. Adverse health outcomes or manifestations of exogenous estrogen in infants exposed to CHCs through breast milk have not been demonstrated; however, studies have been inadequately designed to determine whether a risk for either serious or subtle long-term effects exists (88).
		Comment: Certain women might be at risk for breastfeeding difficulties, such as women with previous breastfeeding difficulties, certain medical conditions, or certain perinatal complications, and those who deliver preterm. For these women, as for all women, discussions about contraception for breastfeeding women should include information about risks, benefits, and alternatives.
Postpartum (nonbreastfeeding women) a. <21 days postpartum	4	Evidence: One study examined use of CHCs during the postpartum period and found that VTE rates were higher for CHC users compared with nonusers at all time points postpartum (89). Rates were significantly different only after 13 weeks postpartum; however, the numbers needed to harm were lowest in the first 6 weeks postpartum. VTE risk is increased during pregnancy and the postpartum period; this risk is most pronounced in the first 3 weeks after delivery, decreasing to near baseline levels by 42 days postpartum (90–94). Risk for pregnancy during the first 21 days postpartum is very low but increases after that point; ovulation before first menses is common (95).
<ul> <li>b. 21–42 days postpartum</li> <li>i. With other risk factors for VTE (e.g., age ≥35 years, previous VTE, thrombophilia, immobility, transfusion at delivery, peripartum</li> </ul>	3	<b>Clarification:</b> For women with other risk factors for VTE, these risk factors might increase the classification to a category 4.
cardiomyopathy, BMI ≥30 kg/m² postpartum hemorrhage, postcesarean delivery, preeclampsia, or smoking)		Evidence: One study examined use of CHCs during the postpartum period and found that VTE rates were higher for CHC users compared with nonusers at all time points postpartum (89). Rates were significantly different only after 13 weeks postpartum; however, the numbers needed to harm were lowest in the first 6 weeks postpartum. VTE risk is increased during pregnancy and the postpartum period; this risk is most pronounced in the first 3 weeks after delivery, decreasing to near baseline levels by 42 days postpartum (90–94).
ii. Without other risk factors for VTE	2	Evidence: One study examined use of CHCs during the postpartum period and found that VTE rates were higher for CHC users compared with nonusers at all time points postpartum (89). Rates were significantly different only after 13 weeks postpartum; however, the numbers needed to harm were lowest in the first 6 weeks postpartum. VTE risk is increased during pregnancy and the postpartum period; this risk is most pronounced in the first 3 weeks after delivery, decreasing to near baseline levels by 42 days postpartum (90–94).
c. >42 days postpartum	1	——————————————————————————————————————

TABLE D1. (Continued) Classifications for combined hormonal contraceptives, including pill, patch, and ring

Condition	Category CHCs	Clarifications/Evidence/Comments
Postabortion		Clarification: CHCs may be started immediately postabortion.
a. First trimester b. Second trimester c. Immediate postseptic abortion	1 1 1	<b>Evidence:</b> Women who started taking COCs immediately after first trimester medical or surgical abortion did not experience more side effects or adverse vaginal bleeding outcomes or clinically significant changes in coagulation parameters than did women who used a placebo, an IUD, a nonhormonal contraceptive method, or delayed COC initiation (96–102). Limited evidence on women using the ring immediately after first trimester medical or surgical abortion found no serious adverse events and no infection related to use of the combined vaginal ring during 3 cycles of follow-up postabortion (103).
Past ectopic pregnancy	1	Comment: The risk for future ectopic pregnancy is increased among women who have had an ectopic pregnancy in the past. CHCs protect against pregnancy in general, including ectopic gestation.
History of pelvic surgery	1	<del>-</del>
Smoking a. Age <35 years b. Age ≥35 years i. <15 cigarettes per day	2	Evidence: COC users who smoked were at increased risk for cardiovascular diseases, especially myocardial infarction, compared with those who did not smoke. Studies also showed an increased risk for myocardial infarction with increasing number of cigarettes smoked per day (104–116).
ii. ≥15 cigarettes per day	4	
Obesity a. BMI ≥30 kg/m² b. Menarche to <18 years and BMI ≥30 kg/m²	2 2	Evidence: Obese women who use COCs are more likely than obese women who do not use COCs to experience VTE. Research examining the interaction between COCs and BMI on VTE risk is limited, particularly for women in the highest BMI categories (BMI ≥35 kg/m²). Although the absolute risk for VTE in otherwise healthy women of reproductive age is small, obese women are at 2–3 times higher risk for VTE than normal weight women regardless of COC use. Limited evidence suggests that obese women who use COCs do not have a higher risk for acute myocardial infarction or stroke than do obese nonusers (117). Limited evidence suggests that effectiveness of some COC formulations might decrease with increasing BMI, however the observed reductions in effectiveness are minimal and evidence is conflicting (118–125). Effectiveness of the patch might be reduced in women >90 kg (126). Limited evidence suggests obese women are no more likely
History of bariatric surgery This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).  a. Restrictive procedures: decrease storage capacity of the stomach (vertical banded gastroplasty, laparoscopic adjustable gastric band, or laparoscopic sleeve gastrectomy)	1	to gain weight during COC or vaginal ring use than normal weight or overweight women (117,127).  Evidence: Limited evidence demonstrated no substantial decrease in effectiveness of oral contraceptives among women who underwent laparoscopic placement of an adjustable gastric band (128).
b. Malabsorptive procedures: decrease absorption of nutrients and calories by shortening the functional length of the small intestine (Roux-en-Y gastric bypass or biliopancreatic diversion)	COCs: 3 Patch and ring: 1	Evidence: Limited evidence demonstrated no substantial decrease in effectiveness of oral contraceptives among women who underwent a biliopancreatic diversion; however, evidence from pharmacokinetic studies reported conflicting results of oral contraceptive effectiveness among women who underwent a jejunoileal bypass (128).
		Comment: Bariatric surgical procedures involving a malabsorptive component have the potential to decrease oral contraceptive effectiveness, perhaps further decreased by postoperative complications, such as long-term diarrhea or vomiting
Cardiovascular Disease		
<b>Multiple risk factors for atherosclerotic cardiovascular disease</b> (e.g., older age, smoking, diabetes, hypertension, low HDL, high LDL, or high triglyceride levels)	3/4	Clarification: When a woman has multiple major risk factors, any of which alone would substantially increase her risk for cardiovascular disease, use of CHCs might increase her risk to an unacceptable level. However, a simple addition of categories for multiple risk factors is not intended; for example, a combination of two category 2 risk factors might not necessarily warrant a higher category.
		Clarification: The recommendations apply to known preexisting medical conditions or characteristics. Few if any screening tests are needed before initiation of contraception. See the <i>U.S. Selected Practice Recommendations for Contraceptive Use</i> (http://www.cdc.gov/reproductivehealth/unintendedpregnancy/usspr.htm).

TABLE D1. (Continued) Classifications for combined hormonal contraceptives, including pill, patch, and ring

Condition	Category CHCs	Clarifications/Evidence/Comments
Hypertension Systolic blood pressure ≥160 mm Hg or diastolic blood pressure ≥100 mm Hg are associated with increased risk for adverse health events as a result of pregnancy (Box 2).		
a. Adequately controlled hypertension	3	<b>Clarification:</b> For all categories of hypertension, classifications are based on the assumption that no other risk factors exist for cardiovascular disease. When multiple risk factors do exist, risk for cardiovascular disease might increase substantially. A single reading of blood pressure level is not sufficient to classify a woman as hypertensive.
		Clarification: Women adequately treated for hypertension are at reduced risk for acute myocardial infarction and stroke compared with untreated women.  Although no data exist, CHC users with adequately controlled and monitored hypertension should be at reduced risk for acute myocardial infarction and stroke compared with untreated hypertensive CHC users.
		<b>Evidence:</b> Among women with hypertension, COC users were at higher risk than nonusers for stroke, acute myocardial infarction, and peripheral arterial disease (104,106,113–116,129–143). Discontinuation of COCs in women with hypertension might improve blood pressure control (144).
b. Elevated blood pressure levels (properly taken measurements) i. Systolic 140–159 mm Hg or diastolic 90–99 mm Hg ii. Systolic ≥160 mm Hg or diastolic ≥100 mm Hg c. Vascular disease	3 4 4	Clarification: For all categories of hypertension, classifications are based on the assumption that no other risk factors exist for cardiovascular disease. When multiple risk factors do exist, risk for cardiovascular disease might increase substantially. A single reading of blood pressure level is not sufficient to classify a woman as hypertensive.
		<b>Evidence:</b> Among women with hypertension, COC users were at higher risk than nonusers for stroke, acute myocardial infarction, and peripheral arterial disease (104,106,113–116,129–143). Discontinuation of COCs in women with hypertension might improve blood pressure control (144).
<b>History of high blood pressure during pregnancy</b> (when current blood pressure is measurable and normal)	2	<b>Evidence:</b> Women with a history of high blood pressure in pregnancy who also used COCs had a higher risk for myocardial infarction and VTE than did COC users who did not have a history of high blood pressure during pregnancy. The absolute risks for acute myocardial infarction and VTE in this population remained small (115,130,142,143,145–151).
Deep venous thrombosis/Pulmonary embolism  a. History of DVT/PE, not receiving anticoagulant therapy i. Higher risk for recurrent DVT/PE (one or more risk factors)  • History of estrogen-associated DVT/PE  • Pregnancy-associated DVT/PE  • Idiopathic DVT/PE  • Known thrombophilia, including antiphospholipid syndrome  • Active cancer (metastatic, receiving therapy, or within 6 months after clinical remission), excluding nonmelanoma skin cancer	4	_
<ul> <li>History of recurrent DVT/PE</li> <li>Lower risk for recurrent DVT/PE (no risk factors)</li> </ul>	3	_
b. Acute DVT/PE	4	_
c. DVT/PE and established anticoagulant therapy for at least 3 months i. Higher risk for recurrent DVT/PE (one or more risk factors)  • Known thrombophilia, including antiphospholipid syndrome  • Active cancer (metastatic, receiving therapy, or within 6 months after clinical remission), excluding nonmelanoma skin cancer  • History of recurrent DTV/PE	4	Clarification: Women using anticoagulant therapy are at risk for gynecologic complications of therapy, such as hemorrhagic ovarian cysts and severe menorrhagia. Hormonal contraceptive methods can be of benefit in preventing or treating these complications. When a contraceptive method is used as a therapy, rather than solely to prevent pregnancy, the risk/benefit ratio might differ and should be considered on a case-by-case basis.
ii. Lower risk for recurrent DVT/PE (no risk factors)	3 2	<b>Comment:</b> Some conditions that increase the risk for DTV/PE are heritable.
d. Family history (first-degree relatives) e. Major surgery	2	Comment. Some conditions that increase the fisk for DTV/PE are nentable.
i. With prolonged immobilization	4	_
ii. Without prolonged immobilization	2	_
f. Minor surgery without immobilization  Known thrombogonic mutations (e.g., factor) / Leiden; prothrombin	1 4	Clarification: Pouting screening is not appropriate because of the varity of the
<b>Known thrombogenic mutations</b> (e.g., factor V Leiden; prothrombin mutation; and protein S, protein C, and antithrombin deficiencies)	4	<b>Clarification</b> : Routine screening is not appropriate because of the rarity of the conditions and the high cost of screening.
This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).		<b>Evidence:</b> Among women with thrombogenic mutations, COC users had a twofold to twentyfold higher risk for thrombosis than did nonusers (152–175).
Superficial venous disorders		
a. Varicose veins	1	<b>Evidence:</b> One study suggested that among women with varicose veins, the rate of VTE and superficial venous thrombosis was higher in oral contraceptive users compared with nonusers; however, statistical significance was not reported and the number of events was small (176).

TABLE D1. (Continued) Classifications for combined hormonal contraceptives, including pill, patch, and ring

Condition	Category CHCs	Clarifications/Evidence/Comments
b. Superficial venous thrombosis (acute or history)	3	Clarification: Superficial venous thrombosis might be associated with an increased risk for VTE. If a woman has risk factors for concurrent DVT (e.g., known thrombophilia or cancer) or has current or history of DVT, see recommendations for DVT/PE. Superficial venous thrombosis associated with a peripheral intravenous catheter is less likely to be associated with additional thrombosis and use of CHCs may be considered.
		<b>Evidence:</b> One study demonstrated that among women with superficial venous thrombosis, the risk for VTE was higher in oral contraceptive users compared with nonusers (176).
Current and history of ischemic heart disease This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	4	_
Stroke (history of cerebrovascular accident) This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2). Valvular heart disease	4	_
Complicated valvular heart disease is associated with increased risk for adverse health events as a result of pregnancy (Box 2).		
a. Uncomplicated	2	_
b. Complicated (pulmonary hypertension, risk for atrial fibrillation, or history of subacute bacterial endocarditis)	4	<b>Comment:</b> Among women with valvular heart disease, CHC use may further increase the risk for arterial thrombosis; women with complicated valvular heart disease are at greatest risk.
Peripartum cardiomyopathy This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).  a. Normal or mildly impaired cardiac function (New York Heart Association Functional Class I or II: patients with no limitation of activities or patients with slight, mild limitation of activity) (178)		<b>Evidence:</b> No direct evidence exists about the safety of CHCs among women with peripartum cardiomyopathy. Limited indirect evidence from noncomparative studies of women with cardiac disease demonstrated few cases of hypertension and transient ischemic attack in women with cardiac disease using COCs. No cases of heart failure were reported (177).
i. <6 months	4	Comment: COCs might increase fluid retention in healthy women; fluid retention
ii. ≥6 months	3	may worsen heart failure in women with peripartum cardiomyopathy. COCs might induce cardiac arrhythmias in healthy women; women with peripartum
b. Moderately or severely impaired cardiac function (New York Heart Association Functional Class III or IV: patients with marked limitation of activity or patients who should be at complete rest) (178)	4	cardiomyopathy have a high incidence of cardiac arrhythmias.
Rheumatic Diseases Systemic lupus erythematosus This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).		
a. Positive (or unknown) antiphospholipid antibodies	4	Clarification: Persons with SLE are at increased risk for ischemic heart disease, stroke, and VTE. Categories assigned to such conditions in U.S. MEC should be the same for women with SLE who have these conditions. For all subconditions of SLE, classifications are based on the assumption that no other risk factors for cardiovascular disease are present; these classifications must be modified in the presence of such risk factors. Many women with SLE can be considered good candidates for most contraceptive methods, including hormonal contraceptives (179–197).
		<b>Evidence:</b> Antiphospholipid antibodies are associated with a higher risk for both arterial and venous thrombosis (198,199).
b. Severe thrombocytopenia	2	Clarification: Persons with SLE are at increased risk for ischemic heart disease, stroke, and VTE. Categories assigned to such conditions in U.S. MEC should be the same for women with SLE who have these conditions. For all subconditions of SLE, classifications are based on the assumption that no other risk factors for cardiovascular disease are present; these classifications must be modified in the presence of such risk factors. Many women with SLE can be considered good candidates for most contraceptive methods, including hormonal contraceptives (179–197).
c. Immunosuppressive therapy	2	Clarification: Persons with SLE are at increased risk for ischemic heart disease, stroke, and VTE. Categories assigned to such conditions in U.S. MEC should be the same for women with SLE who have these conditions. For all subconditions of SLE, classifications are based on the assumption that no other risk factors for cardiovascular disease are present; these classifications must be modified in the presence of such risk factors. Many women with SLE can be considered good candidates for most contraceptive methods, including hormonal contraceptives (179–197).
d. None of the above	2	Clarification: Persons with SLE are at increased risk for ischemic heart disease, stroke, and VTE. Categories assigned to such conditions in U.S. MEC should be the same for women with SLE who have these conditions. For all subconditions of SLE, classifications are based on the assumption that no other risk factors for cardiovascular disease are present; these classifications must be modified in the presence of such risk factors. Many women with SLE can be considered good candidates for most contraceptive methods, including hormonal contraceptives (179–197).

TABLE D1. (Continued) Classifications for combined hormonal contraceptives, including pill, patch, and ring

Condition	Category CHCs	Clarifications/Evidence/Comments
Rheumatoid arthritis a. Receiving immunosuppressive therapy	2	<b>Evidence:</b> Limited evidence shows no consistent pattern of improvement or worsening of rheumatoid arthritis with use of oral contraceptives, progesterone, or estrogen (200).
b. Not receiving immunosuppressive therapy  Neurologic Conditions	2	estrogen (200).
Headaches a. Nonmigraine (mild or severe)	1	Clarification: Classification depends on accurate diagnosis of those severe headaches that are migraines and those headaches that are not, as well as diagnosis of ever experiencing aura. Aura is a specific focal neurologic symptom. For more information about headache classification see <i>The International Headache Society Classification, 3rd edition</i> (http://www.ihs-classification.org/_downloads/mixed/International-Headache-Classification-III-ICHD-III-2013-Beta.pdf). Any new headaches or marked changes in headaches should be evaluated.
b. Migraine i. Without aura (This category of migraine includes menstrual migraine.) ii. With aura	2 4	Clarification: Classification depends on accurate diagnosis of those severe headaches that are migraines and those headaches that are not, as well as diagnosis of ever experiencing aura. Aura is a specific focal neurologic symptom. For more information about headache classification see <i>The International Headache Society Classification, 3rd edition</i> (http://www.ihs-classification.org/_downloads/mixed/International-Headache-Classification-III-ICHD-III-2013-Beta.pdf). Any new headaches or marked changes in headaches should be evaluated.
		Clarification: Classification is for women without any other risk factors for stroke (e.g., age, hypertension, and smoking).
		Evidence: Among women with migraine, oral contraceptive use is associated with about a threefold increased risk for ischemic stroke compared with nonuse, although most studies did not specify migraine type or oral contraceptive formulation. The only study to examine migraine type found that the risk for ischemic stroke among women with migraine with aura was increased to a similar level among both oral contraceptive users and nonusers, compared with women without migraine (201). The risk for ischemic stroke is increased among women using COCs, compared with women not using COCs (104,202). The risk for ischemic stroke is also increased among women with migraine with aura, compared with women without migraine (203–205). One older meta-analysis found that migraine without aura was associated with an increased risk for ischemic stroke, while two more recent meta-analyses did not find such an association (203–205).
		Comment: Menstrual migraine is a subtype of migraine without aura. For more information, see <i>The International Headache Society Classification, 3rd edition</i> (http://www.ihs-classification.org/_downloads/mixed/International-Headache-Classification-III-ICHD-III-2013-Beta.pdf).
<b>Epilepsy</b> This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1	<b>Clarification:</b> If a woman is taking anticonvulsants, see Drug Interactions section. Certain anticonvulsants lower COC effectiveness. The extent to which patch or ring use is similar to COC use in this regard remains unclear.
Multiple sclerosis a. With prolonged immobility b. Without prolonged immobility	3 1	<b>Evidence:</b> Limited evidence suggests that use of COCs or oral contraceptives (type not specified) among women with multiple sclerosis does not worsen the clinical course of disease (206).
		<b>Comment:</b> No data exist that evaluate the increased risk for VTE among women with multiple sclerosis using CHCs. However, women with multiple sclerosis are at higher risk than unaffected women for VTE.
Depressive Disorders Depressive disorders	1	<b>Clarification</b> : If a woman is receiving psychotropic medications or St. John's wort, see Drug Interactions section.
		<b>Evidence</b> : COC use was not associated with increased depressive symptoms in women with depression or scoring above threshold levels on a validated depression screening instrument compared with baseline or with nonusers with depression. One small study of women with bipolar disorder found that oral contraceptives did not significantly change mood across the menstrual cycle (207).
Reproductive Tract Infections and Disorders		
Vaginal bleeding patterns a. Irregular pattern without heavy bleeding	1	Comment: Irregular menstrual bleeding patterns are common among healthy women.
b. Heavy or prolonged bleeding (includes regular and irregular patterns)	1	<b>Clarification:</b> Unusually heavy bleeding should raise the suspicion of a serious underlying condition.
		<b>Evidence:</b> A Cochrane Collaboration Review identified one randomized controlled trial evaluating the effectiveness of COC use compared with naproxen and danazol in treating menorrhagia. Women with menorrhagia did not report worsening of the condition or any adverse events related to COC use (208).

TABLE D1. (Continued) Classifications for combined hormonal contraceptives, including pill, patch, and ring

Condition	Category CHCs	Clarifications/Evidence/Comments
Unexplained vaginal bleeding (suspicious for serious condition) before evaluation	2	Clarification: If pregnancy or an underlying pathological condition (e.g., pelvic malignancy) is suspected, it must be evaluated and the category adjusted after evaluation.
		Comment: No conditions that cause vaginal bleeding will be worsened in the short-term by use of CHCs.
Endometriosis	1	<b>Evidence:</b> A Cochrane Collaboration Review identified one randomized controlled trial evaluating the effectiveness of COC use compared with a gonadotropin-releasing hormone analog in treating the symptoms of endometriosis. Women with endometriosis did not report worsening of the condition or any adverse events related to COC use (209).
Benign ovarian tumors (including cysts)	1	. ,
Severe dysmenorrhea	1	<b>Evidence:</b> Risk for side effects with COC use was not higher among women with dysmenorrhea than among women not using COCs. Some COC users had a reduction in pain and bleeding (210,211).
Gestational trophoblastic disease This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2). a. Suspected gestational trophoblastic disease (immediate		Clarification: For all subconditions of gestational trophoblastic disease, classifications are based on the assumption that women are under close medical supervision because of the need for monitoring of $\beta$ -hCG levels for appropriate disease surveillance.
postevacuation) i. Uterine size first trimester ii. Uterine size second trimester b. Confirmed gestational trophoblastic disease (after initial evacuation and during monitoring) i. Undetectable/nonpregnant β-hCG levels ii. Decreasing β-hCG levels iii. Persistently elevated β-hCG levels or malignant disease, with no evidence or suspicion of intrauterine disease iv. Persistently elevated β-hCG levels or malignant disease, with evidence or suspicion of intrauterine disease	1 1 1 1 1	<b>Evidence:</b> After molar pregnancy evacuation, the balance of evidence found COC use did not increase the risk for postmolar trophoblastic disease, and $\beta$ -hCG levels regressed more rapidly in some COC users than in nonusers (212). Limited evidence suggests that use of COCs during chemotherapy does not significantly affect the regression or treatment of postmolar trophoblastic disease compared with women who used a nonhormonal contraceptive method or DMPA during chemotherapy (212)
evidence or suspicion of intrauterine disease  Cervical ectropion	1	<b>Comment:</b> Cervical ectropion is not a risk factor for cervical cancer, and restriction of CHC use is unnecessary.
Cervical intraepithelial neoplasia	2	Evidence: Among women with persistent human papillomavirus infection, long-term COC use (≥5 years) might increase the risk for carcinoma in situ and invasive carcinoma (213). Limited evidence on women with low-grade squamous intraepithelial lesions found use of the vaginal ring did not worsen the condition (9).
Cervical cancer (awaiting treatment)	2	Comment: Theoretical concern exists that CHC use might affect prognosis of the existing disease. While awaiting treatment, women may use CHCs. In general, treatment of this condition can render a woman sterile.
<b>Breast disease</b> Breast cancer is associated with increased risk for adverse health events as a result of pregnancy (Box 2).		
a. Undiagnosed mass	2	Clarification: The woman should be evaluated as early as possible.
b. Benign breast disease c. Family history of cancer	1 1	Evidence: Women with breast cancer susceptibility genes (e.g., BRCA1 and BRCA2) have a higher baseline risk for breast cancer than women without these genes. The baseline risk for breast cancer is also higher among women with a family history of breast cancer than among those who do not have such a history. However, evidence does not suggest that the increased risk for breast cancer among women with either a family history of breast cancer or breast cancer susceptibility genes is modified by the use of COCs (214–231).
d. Breast cancer i. Current ii. Past and no evidence of current disease for 5 years	4 3	<b>Comment:</b> Breast cancer is a hormonally sensitive tumor, and the prognosis for women with current or recent breast cancer might worsen with CHC use.
Endometrial hyperplasia	1	_
Endometrial cancer This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1	Comment: COC use reduces the risk for endometrial cancer; whether patch or ring use reduces the risk for endometrial cancer is not known. While awaiting treatment, women may use CHCs. In general, treatment of this condition renders a woman sterile.
<b>Ovarian cancer</b> This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1	Comment: COC use reduces the risk for ovarian cancer; whether patch or ring use reduces the risk for ovarian cancer is not known. While awaiting treatment, women may use CHCs. In general, treatment of this condition can render a woman sterile.
Uterine fibroids	1	$\label{lem:comment:cocs} \textbf{Comment:} \ \ \text{COCs do not appear to cause growth of uterine fibroids, and patch and ring also are not expected to cause growth.}$

TABLE D1. (Continued) Classifications for combined hormonal contraceptives, including pill, patch, and ring

Condition	Category CHCs	Clarifications/Evidence/Comments
Pelvic inflammatory disease		Comment: COCs might reduce the risk for PID among women with STDs but do
a. Past PID		not protect against HIV or lower genital tract STDs. Whether use of patch or ring
i. With subsequent pregnancy	1	reduces the risk for PID among women with STDs is unknown; however, they do
ii. Without subsequent pregnancy	1	not protect against HIV or lower genital tract STDs.
b. Current PID	1	
Sexually transmitted diseases		
a. Current purulent cervicitis or chlamydial infection or gonococcal infection	1	_
b. Vaginitis (including <i>Trichomonas vaginalis</i> and bacterial vaginosis)	1	_
c. Other factors related to STDs	1	_
HIV		
High risk for HIV	1	Evidence: Overall, evidence does not support an association between oral
THIS I THE	'	contraceptives and risk for HIV acquisition (232).
IIIV. C. C.		
HIV infection  For women with HIV infection who are not clinically well or not receiving	1	Clarification: Drug interactions might exist between hormonal contraceptives and ARV drugs; see Drug Interactions section.
ARV therapy, this condition is associated with increased risk for adverse		And drugs, see Drug interactions section.
health events as a result of pregnancy (Box 2).		Evidence: Overall, evidence does not support an association between COC use an
		progression of HIV. Limited direct evidence does not support an association
		between COC use and transmission of HIV to noninfected partners; studies measuring genital viral shedding as a proxy for infectivity have had mixed results.
		Studies measuring whether hormonal contraceptive methods affect plasma HIV
		viral load generally have found no effect (233–235).
Other Infections		
Schistosomiasis		
Schistosomiasis with fibrosis of the liver is associated with increased risk		
for adverse health events as a result of pregnancy (Box 2).		
a. Uncomplicated	1	Evidence: Among women with uncomplicated schistosomiasis, COC use had no
		adverse effects on liver function (236–242).
b. Fibrosis of the liver (if severe, see Cirrhosis section)	1	
Tuberculosis This condition is associated with increased risk for adverse health events		Clarification: If a woman is taking rifampin, see Drug Interactions section. Rifampin is likely to decrease COC effectiveness. The extent to which patch or ring use is
as a result of pregnancy (Box 2).		similar to COC use in this regard remains unclear.
a. Nonpelvic	1	Similar to co c use in this regular terrains arrelean
b. Pelvic	1	
Malaria	1	_
Endocrine Conditions		
Diabetes		
Insulin-dependent diabetes; diabetes with nephropathy, retinopathy, or		
neuropathy; diabetes with other vascular disease; or diabetes of		
>20 years' duration are associated with increased risk for adverse health		
events as a result of pregnancy (Box 2).	1	Evidence: The development of non-insulin dependent diabetes in woman with a
a. History of gestational disease	I	<b>Evidence:</b> The development of non-insulin-dependent diabetes in women with a history of gestational diabetes is not increased by use of COCs (243–250). Likewise,
		lipid levels appear to be unaffected by COC use (251–253).
L. Alexandra Process		
b. Nonvascular disease	2	Evidence: Among women with insulin-dependent or non-insulin-dependent diabetes, COC use had limited effect on daily insulin requirements and no effect or
i. Non-insulin dependent	2	long-term diabetes control (e.g., glycosylated hemoglobin levels) or progression to
ii. Insulin dependent	2	retinopathy. Changes in lipid profile and hemostatic markers were limited, and
		most changes remained within normal values (254–263).
c. Nephropathy, retinopathy, or neuropathy	3/4	Clarification: The category should be assessed according to the severity of the condition.
d. Other vascular disease or diabetes of >20 years' duration	3/4	Clarification: The category should be assessed according to the severity of the condition
Thyroid disorders		
a. Simple goiter	1	_
b. Hyperthyroid	1	_
c. Hypothyroid	1	<del>-</del> -
Gastrointestinal Conditions		
Inflammatory bowel disease (ulcerative colitis or Crohn's disease)	2/3	Clarification: For women with mild IBD and with no other risk factor for VTE, the
		benefits of CHC use generally outweigh the risks (category 2). However, for womer
		with IBD who are at increased risk for VTE (e.g., those with active or extensive
		disease, surgery, immobilization, corticosteroid use, vitamin deficiencies, or fluid depletion), the risks of CHC use generally outweigh the benefits (category 3).
		depletion), the risks of Cric use generally outwelgh the benefits (category 3).
		Evidence: Risk for disease relapse was not significantly higher among women with
		IBD using oral contraceptives (most studies did not specify type) than among
		nonusers (264). Absorption of COCs among women with mild ulcerative colitis and
		no or small ileal resections was similar to the absorption among healthy women (264). Findings might not apply to women with Crohn's disease or more extensive
		bowel resections. No data exist that evaluate the increased risk for VTE among
		women with IBD using CHCs. However, women with IBD are at higher risk than
		unaffected women for VTE (264).

TABLE D1. (Continued) Classifications for combined hormonal contraceptives, including pill, patch, and ring

Condition	Categ	gory CHCs	Clarifications/Evidence/Comments	
Gallbladder disease a. Symptomatic			<b>Comment:</b> CHCs might cause a small increased risk for gallbladder disease. CHCs might worsen existing gallbladder disease.	
i. Treated by cholecystectomy		2		
ii. Medically treated		3		
iii. Current		3		
b. Asymptomatic		2		
History of cholestasis				
a. Pregnancy related		2	<b>Comment:</b> History of pregnancy-related cholestasis might predict an increased ris for COC-related cholestasis.	
b. Past COC related		3	<b>Comment:</b> History of COC-related cholestasis predicts an increased risk with subsequent COC use.	
Viral hepatitis a. Acute or flare	Initiation 3/4	Continuation 2	<b>Clarification (initiation):</b> The category should be assessed according to the severit of the condition.	
			<b>Evidence:</b> Data suggest that in women with chronic hepatitis, COC use does not increase the rate or severity of cirrhotic fibrosis, nor does it increase the risk for hepatocellular carcinoma. For women who are carriers, COC use does not appear to trigger liver failure or severe dysfunction. Evidence is limited for COC use during active hepatitis (265).	
b. Carrier	1	1	<b>Evidence:</b> Data suggest that in women with chronic hepatitis, COC use does not increase the rate or severity of cirrhotic fibrosis, nor does it increase the risk for hepatocellular carcinoma. For women who are carriers, COC use does not appear to trigger liver failure or severe dysfunction. Evidence is limited for COC use during active hepatitis (265).	
c. Chronic	1	1	<b>Evidence:</b> Data suggest that in women with chronic hepatitis, COC use does not increase the rate or severity of cirrhotic fibrosis, nor does it increase the risk for hepatocellular carcinoma. For women who are carriers, COC use does not appear to trigger liver failure or severe dysfunction. Evidence is limited for COC use during active hepatitis (265).	
Cirrhosis				
Severe cirrhosis is associated with increased risk for adverse health events as a result of pregnancy (Box 2).				
a. Mild (compensated)		1	<del>-</del>	
b. Severe (decompensated) Liver tumors		4	_	
Hepatocellular adenoma and malignant liver tumors are associated with increased risk for adverse health events as a result of pregnancy (Box 2).  a. Benign				
i. Focal nodular hyperplasia		2	<b>Evidence:</b> Limited direct evidence suggests that hormonal contraceptive use does not influence either progression or regression of liver lesions among women with focal nodular hyperplasia (266).	
ii. Hepatocellular adenoma		4	—	
b. Malignant (hepatoma)		4	_	
		•		
Respiratory Conditions Cystic fibrosis		1	Clarification. Dorsons with systic fibracis are at increased risk for diabetes liver	
This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).		1	Clarification: Persons with cystic fibrosis are at increased risk for diabetes, liver disease, gallbladder disease, and VTE (particularly related to use of central venous catheters) and are frequently prescribed antibiotics. Categories assigned to such conditions in U.S. MEC should be the same for women with cystic fibrosis who have these conditions. For cystic fibrosis, classifications are based on the assumption that no other conditions are present; these classifications must be modified in the presence of such conditions.	
			<b>Clarification:</b> Certain drugs to treat cystic fibrosis (e.g., lumacaftor) might reduce effectiveness of hormonal contraceptives, including oral, injectable, transdermal, and implantable contraceptives.	
			<b>Evidence:</b> Limited evidence suggests that use of COCs or oral contraceptives (type not specified) among women with cystic fibrosis is not associated with worsening of disease severity. Very limited evidence suggests that cystic fibrosis does not impair the effectiveness of hormonal contraception (267).	
Anemias				
Thalassemia		1	Comment: Anecdotal evidence from countries where thalassemia is prevalent	
Sickle cell disease This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).		2	indicates that COC use does not worsen the condition. —	
Iron deficiency anemia		1	Comment: CHC use might decrease menstrual blood loss.	
Solid Organ Transplantation Solid organ transplantation This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).				

TABLE D1. (Continued) Classifications for combined hormonal contraceptives, including pill, patch, and ring

Condition	Category CHCs	Clarifications/Evidence/Comments
a. Complicated: graft failure (acute or chronic), rejection, cardiac allograft vasculopathy	4	Evidence: Limited evidence of COC and patch users indicated no overall changes in biochemical measures. However, one study reported discontinuations of COC use in two (8%) of 26 women as a result of serious medical complications, and in one case report, a woman developed cholestasis associated with high-dose COC use (268).
b. Uncomplicated	2	Clarification: Women with Budd-Chiari syndrome should not use CHCs because of the increased risk for thrombosis.
		<b>Evidence:</b> Limited evidence of COC and patch users indicated no overall changes in biochemical measures. However, one study reported discontinuations of COC use in two (8%) of 26 women as a result of serious medical complications, and in one case report, a woman developed cholestasis associated with high-dose COC use (268).
Drug Interactions		
Antiretroviral therapy		Comment: These recommendations generally are for ARV agents used alone. However, most women receiving ARV therapy are using multiple drugs in combination. In general, whether interactions between ARVs and hormonal contraceptives differ when ARVs are given alone or in combination is unknown.
a. Nucleoside reverse transcriptase inhibitors (NRTIs)		
i. Abacavir (ABC)	1	<b>Evidence:</b> NRTIs do not appear to have significant risk for interactions with
ii. Tenofovir (TDF)	1	hormonal contraceptive methods (269–274).
iii. Zidovudine (AZT)	1	
iv. Lamivudine (3TC)	1	
v. Didanosine (DDI)	1	
vi. Emtricitabine (FTC) vii. Stavudine (D4T)	1 1	
b. Nonnucleoside reverse transcriptase inhibitors (NNRTIs)	,	
i. Efavirenz (EFV)	2	<b>Clarification:</b> Evidence suggests drug interactions between EFV and certain hormonal contraceptives. These interactions might reduce the effectiveness of the hormonal contraceptive.
		Evidence: Two studies suggested that pregnancy rates might be higher among women using COCs and EFV compared with COCs alone, although one study foun no difference in pregnancy rates (275–277) Two studies found conflicting results o ovulations in women receiving COCs and EFV compared with EFV alone (278,279). Two pharmacokinetic studies demonstrated decreases in ethinyl estradiol and progestin concentrations in women receiving COCs and EFV compared with COCs alone (279,280). Pharmacokinetic studies demonstrated generally no changes in EFV concentrations with concomitant COC use (279,280).
ii. Etravirine (ETR)	1	<b>Evidence:</b> One study demonstrated no clinically relevant pharmacokinetic or pharmacodynamic changes in women using COCs and ETR compared with COCs alone (281).
iii. Nevirapine (NVP)	1	Evidence: Five studies found no significant differences in pregnancy rates among women using COCs and NVP compared with women using COCs alone (275–277,282,283). Three studies reported no ovulations among women receiving COCs and NVP (278,283,284). Two pharmacokinetic studies demonstrated decreased concentrations of ethinyl estradiol and progestin among women using COCs and NVP compared with COCs alone, and one study found no change in contraceptive hormone concentrations (278,284,285). Pharmacokinetic studies demonstrated generally no changes in NVP concentrations with concomitant COC use (278,285,286).
iv. Rilpivirine (RPV)	1	<b>Evidence:</b> One study demonstrated no clinical significant pharmacokinetic changes or adverse events in women using COCs and RPV compared with COCs
c. Ritonavir-boosted protease inhibitors		alone (287).
i. Ritonavir-boosted atazanavir (ATV/r)	2	<b>Clarification:</b> Theoretically, drug interactions might occur between certain ritonavir-boosted protease inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive.
		<b>Evidence:</b> One pharmacokinetic study demonstrated decreased estrogen but increased progestin concentrations in women using COCs and ATV/r compared with COCs alone (288).
ii. Ritonavir-boosted darunavir (DRV/r)	2	<b>Clarification:</b> Theoretically, drug interactions might occur between certain ritonavir-boosted protease inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive.
		Evidence: One pharmacokinetic study demonstrated no change in follicle-stimu- lating hormone or luteinizing hormone but decreases in ethinyl estradiol and norethindrone in women using COCs with DRV/r compared with COCs alone (289).

TABLE D1. (Continued) Classifications for combined hormonal contraceptives, including pill, patch, and ring

Condition	Category CHCs	Clarifications/Evidence/Comments
iii. Ritonavir-boosted fosamprenavir (FPV/r)	2	Clarification: Theoretically, drug interactions might occur between certain ritonavir-boosted protease inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive.
		<b>Evidence:</b> Information from the package label states that both ethinyl estradiol and norethindrone concentrations decreased with concurrent administration of COCs and FPV/r (290).
iv. Ritonavir-boosted Iopinavir (LPV/r)	1	Evidence: One study demonstrated a non-significant increase in pregnancy rates among women using COCs and LPV/r compared with COCs alone (275). One stud demonstrated no ovulations in women using the combined hormonal patch and LPV/r compared with combined hormonal patch alone; ethinyl estradiol concentrations for COC and patch users decreased but norelgestromin concentrations increased with use of the patch (291).
v. Ritonavir-boosted saquinavir (SQV/r)	2	<b>Clarification:</b> Theoretically, drug interactions might occur between certain ritonavir-boosted protease inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive.
		<b>Evidence:</b> One pharmacokinetic study demonstrated no change in SQV concentrations in women using COC and SQV compared with COCs alone (292).
iv. Ritonavir-boosted tipranavir (TPV/r)	2	<b>Clarification:</b> Theoretically, drug interactions might occur between certain ritonavir-boosted protease inhibitors and certain hormonal contraceptives that might reduce the effectiveness of the hormonal contraceptive.
		<b>Evidence:</b> Information from the package label states that ethinyl estradiol concentrations decrease but norethindrone concentrations increased with concurrent administration of COCs and TPV/r (293).
d. Protease inhibitors without ritonavir		
i. Atazanavir (ATV)	2	<b>Clarification:</b> Theoretical concern exists that increased levels of ethinyl estradiol because of interactions with ATV might increase the risk for adverse events.
		<b>Evidence:</b> Information from the package label states that there are inconsistent changes in ethinyl estradiol concentrations and increases in progestin concentrations with concurrent administration of two different COCs and ATV (294).
		Comment: When ATV is administered with Cobicistat, theoretical concern exists f a drug interaction with hormonal contraceptives. Cobicistat is an inhibitor of CYP3A and CYP2D6 and could theoretically increase contraceptive hormone level However, its effects on CYP enzymes and drug levels may vary when combined with other ARVs.
ii. Fosamprenavir (FPV)	3	Clarification: Concern exists that interactions between FPV and hormonal contraceptives leading to decreased levels of FPV might diminish effectiveness of the ARV drug.
		<b>Evidence:</b> Information from the package label states that amprenavir concentrations decreased with concurrent administration of COCs and amprenavir. Norethindrone concentrations increased and ethinyl estradiol concentrations did not change (290).
iii. Indinavir (IDV)	1	Evidence: One small study found no pregnancies in women using COCs and IDV (277)
iv. Nelfinavir (NFV)	2	<b>Clarification:</b> Evidence suggests drug interactions between certain protease inhibitors and certain hormonal contraceptives. These interactions might reduce the effectiveness of the hormonal contraceptive.
		<b>Evidence:</b> One small study suggested that women using COCs and NFV may have had higher pregnancy rates than those using COCs alone (277).
e. CCR5 co-receptor antagonists i. Maraviroc (MVC) f. HIV integrase strand transfer inhibitors	1	Evidence: COC concentrations were not altered by co-administration with MVC (29:
i. Raltegravir (RAL)	1	<b>Evidence:</b> One pharmacokinetic study demonstrated increased concentrations of norgestimate and no change in ethinyl estradiol among women using COCs and RAL compared with COCs alone (296).
ii. Dolutegravir (DTG)	1	<b>Evidence:</b> One study demonstrated no clinically relevant pharmacokinetic or pharmacodynamic changes in women using COCs and DTG compared with COCs alone (297).

TABLE D1. (Continued) Classifications for combined hormonal contraceptives, including pill, patch, and ring

Condition	Category CHCs	Clarifications/Evidence/Comments
iii. Elvitegravir (EVG)	1	<b>Evidence:</b> Information from the package label states that ethinyl estradiol concentrations decreased and norgestimate concentrations increased with concurrent administration of COCs and EVG (298).
		Comment: When ATV is administered with Cobicistat, theoretical concern exists for a drug interaction with hormonal contraceptives. Cobicistat is an inhibitor of CYP3A and CYP2D6 and could theoretically increase contraceptive hormone levels. However, its effects on CYP enzymes and drug levels may vary when combined with other ARVs.
g. Fusion inhibitors i. Enfuvirtide	1	_
Anticonvulsant therapy		
a. Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, oxcarbazepine)	3	Clarification: Although the interaction of certain anticonvulsants with CHCs is not harmful to women, it is likely to reduce the effectiveness of CHCs. Use of other contraceptives should be encouraged for women who are long-term users of any of these drugs. When a COC is chosen, a preparation containing a minimum of 30 $\mu$ g ethinyl estradiol should be used.
		<b>Evidence:</b> Use of certain anticonvulsants might decrease the effectiveness of COCs (299–302).
b. Lamotrigine	3	Clarification: The recommendation for lamotrigine applies only for situations where lamotrigine monotherapy is taken concurrently with COCs. Anticonvulsant treatment regimens that combine lamotrigine and non–enzyme-inducing antiepileptic drugs (e.g., sodium valproate) do not interact with COCs.
		<b>Evidence:</b> Pharmacokinetic studies show levels of lamotrigine decrease significantly during COC use (303–307). Some women who used both COCs and lamotrigine experienced increased seizure activity in one trial (303).
Antimicrobial therapy		
a. Broad-spectrum antibiotics	1	<b>Evidence:</b> Most broad-spectrum antibiotics do not affect the contraceptive effectiveness of COCs (308–344), patch (345), or ring (346).
b. Antifungals	1	<b>Evidence:</b> Studies of antifungal agents have shown no clinically significant pharmacokinetic interactions with COCs (347–356), or ring (357).
c. Antiparasitics	1	<b>Evidence:</b> Studies of antiparasitic agents have shown no clinically significant pharmacokinetic interactions with COCs (236,358–362).
d. Rifampin or rifabutin therapy	3	Clarification: Although the interaction of rifampin or rifabutin therapy with CHCs is not harmful to women, it is likely to reduce the effectiveness of CHCs. Use of other contraceptives should be encouraged for women who are long-term users of either of these drugs. When a COC is chosen, a preparation containing a minimum of 30 µg ethinyl estradiol should be used.
		<b>Evidence:</b> The balance of the evidence suggests that rifampin reduces the effectiveness of COCs (363–378). Data on rifabutin are limited, but effects on metabolism of COCs are less than with rifampin, and small studies have not shown evidence of ovulation (365,372).
Psychotropic medications		Comment: For many common psychotropic agents, limited or no theoretical concern exists for clinically significant drug interactions when co-administered with hormonal contraceptives. However, either no or very limited data exist examining potential interactions for these classes of medications. For psychotropic agents that are CYP1A2 substrates, such as duloxetine, mirtazapine, ziprasidone, olanzapine, clomipramine, imipramine, and amitriptyline, co-administration with CHCs could theoretically yield increased concentrations of the psychotropic drug. For agents with narrow therapeutic windows, such as tricyclic antidepressants, increased drug concentrations might pose safety concerns that could necessitate closer monitoring.
a. SSRIs	1	<b>Evidence:</b> Limited clinical and pharmacokinetic data do not demonstrate concern for SSRIs decreasing the effectiveness of oral contraceptives. Limited evidence suggests that for women taking SSRIs, the use of hormonal contraceptives was not associated with differences in effectiveness of the SSRI for treatment or in adverse events when compared with women not taking hormonal contraceptives (379).
		Comment: Drugs that are inhibitors of CYP3A4 or CYP2C9 theoretically have the potential to increase levels of contraceptive steroids which might increase adverse events. Fluvoxamine is an SSRI known to be a moderate inhibitor of both CYP3A4 and CYP2C9; however, no clinical or pharmacokinetic studies were identified to explore potential drug-drug interactions.

TABLE D1. (Continued) Classifications for combined hormonal contraceptives, including pill, patch, and ring

Condition	Category CHCs	Clarifications/Evidence/Comments
St. John's wort	2	<b>Evidence:</b> Although clinical data are limited, studies with pharmacokinetic and pharmacodynamics outcomes raise concern that St. John's wort might decrease effectiveness of hormonal contraceptives, including increased risk for breakthrough bleeding and ovulation and increased metabolism of estrogen and progestins. Any interactions might be dependent on the dose of St John's wort, and the concentration of active ingredients across types of St. John's wort preparations may vary (380).

Abbreviations: ARV = antiretroviral; BMD = bone mineral density; BMI = body mass index; CHC = combined hormonal contraceptive; COC = combined oral contraceptive; DVT = deep venous thrombosis; hCG = human chorionic gonadotropin; HDL = high-density lipoprotein; HIV = human immunodeficiency virus; IBD = inflammatory bowel disease; LDL = low-density lipoprotein; PE = pulmonary embolism; PID = pelvic inflammatory disease; SLE = systemic lupus erythematosus; SSRI = selective serotonin reuptake inhibitor; STD = sexually transmitted infection; VTE = venous thromboembolism.

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# **Appendix E**

### **Classifications for Barrier Methods**

Classifications for barrier contraceptive methods include those for condoms, which include male latex condoms, male polyurethane condoms, and female condoms; spermicides; and diaphragm with spermicide or cervical cap (Box E1) (Table E1).

Women with conditions that make pregnancy an unacceptable risk should be advised that barrier methods for pregnancy prevention might not be appropriate for those who cannot use them consistently and correctly because of the relatively higher typical-use failure rates of these methods. Women should be counseled that consistent and correct use of the male latex condom reduces the risk for transmission of human immunodeficiency virus (HIV) and other sexually transmitted diseases (STDs). Use of female condoms can provide protection from transmission of STDs, although data are limited.

### BOX E1. Categories for classifying barrier methods

- 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.

TABLE E1. Classifications for barrier methods, including condoms, spermicides, diaphragms (with spermicide), and cap

		Category		
Condition	Condom	Spermicide	Diaphragm (with spermicide)/Cap	
Personal Characteristics and Reproductive History				
Pregnancy	NA	NA	NA	Clarification: None of these methods are relevant for contraception during known pregnancy. However, for women who remain at risk for STDs/HIV during pregnancy, the correct and consistent use of condoms is recommended.
Age				
a. Menarche to <40 years	1	1	1	_
b. ≥40 years	1	1	1	_
Parity				
a. Nulliparous	1	1	1	_
b. Parous	1	1	2	Clarification: Risk for cervical cap failure is higher in parous women than in nulliparous women.
Postpartum (breastfeeding and nonbreastfeeding)				
a. <6 weeks postpartum	1	1	NA	<b>Clarification:</b> Diaphragm and cap are unsuitable until uterine involution is complete.
b. ≥6 weeks postpartum	1	1	1	· <u> </u>
Postabortion				
a. First trimester	1	1	1	_
b. Second trimester	1	1	1	<b>Clarification:</b> Diaphragm and cap are unsuitable until 6 weeks after second trimester abortion.
c. Immediate postseptic abortion	1	1	1	_
Past ectopic pregnancy	1	1	1	_
History of pelvic surgery	1	1	1	_
Smoking				
a. Age <35 years	1	1	1	_
b. Age ≥35 years				
i. <15 cigarettes per day	1	1	1	_
ii. ≥15 cigarettes per day	1	1	1	_
Obesity				Comment: Severe obesity might make diaphragm and
a. BMI ≥30 kg/m <sup>2</sup>	1	1	1	cap placement difficult.
b. Menarche to <18 years and BMI ≥30 kg/m²	1	1	1	

TABLE E1. (Continued) Classifications for barrier methods, including condoms, spermicides, diaphragms (with spermicide), and cap

		Category		
— Condition	Condom	Spermicide	Clarifications/Evidence/Comments	
History of bariatric surgery			spermicide)/Cap	
This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).				
a. Restrictive procedures: decrease storage capacity of the stomach (vertical banded gastroplasty, laparoscopic adjustable gastric band, or laparoscopic sleeve gastrectomy)	1	1	1	_
b. Malabsorptive procedures: decrease absorption of nutrients and calories by shortening the functional length of the small intestine (Roux-en-Y gastric bypass or biliopancreatic diversion)	1	1	1	_
Cardiovascular Disease				
Multiple risk factors for atherosclerotic cardiovascular disease (e.g., older age, smoking, diabetes, hypertension, low HDL, high LDL, or high triglyceride levels) Hypertension Systolic blood pressure ≥160 mm Hg or diastolic blood pressure ≥100 mm Hg are associated with increased risk for	1	1	1	_
adverse health events as a result of pregnancy (Box 2).				
a. Adequately controlled hypertension     b. Elevated blood pressure levels	1	1	1	_
(properly taken measurements)				
i. Systolic 140–159 mm Hg or diastolic 90–99 mm Hg	1	1	1	_
ii. Systolic ≥160 mm Hg or diastolic ≥100 mm Hg	1	1	1	_
c. Vascular disease	1	1	1	_
History of high blood pressure during pregnancy (when current blood pressure is measurable and normal)	1	1	1	_
Deep venous thrombosis/Pulmonary embolism				
a. History of DVT/PE, not receiving anticoagulant therapy	1	1	1	
i. Higher risk for recurrent DVT/PE (one or more risk factors)	ı	ı	ı	_
History of estrogen-associated DVT/PE     Pregnancy-associated DVT/PE     Idiopathic DVT/PE				
Known thrombophilia, including antiphospholipid syndrome				
<ul> <li>Active cancer (metastatic, receiving therapy, or within 6 months after clinical remission), excluding nonmelanoma skin cancer</li> <li>History of recurrent DVT/PE</li> </ul>				
ii. Lower risk for recurrent DVT/PE (no risk factors)	1	1	1	_
b. Acute DVT/PE	1	1	1	_
c. DVT/PE and established anticoagulant therapy for at				
least 3 months				
i. Higher risk for recurrent DVT/PE (one or more risk factors)	1	1	1	
Known thrombophilia, including antiphospholipid syndrome      Active cancer (metastatic receiving therapy, or within)				
<ul> <li>Active cancer (metastatic, receiving therapy, or within 6 months after clinical remission), excluding nonmelanoma skin cancer</li> <li>History of recurrent DVT/PE</li> </ul>				
ii. Lower risk for recurrent DVT/PE (no risk factors)	1	1	1	_
d. Family history (first-degree relatives)	1	1	1	_
e. Major surgery				
i. With prolonged immobilization	1	1	1	_
ii. Without prolonged immobilization	1	1	1	_
f. Minor surgery without immobilization	1	1	1	_

TABLE E1. (Continued) Classifications for barrier methods, including condoms, spermicides, diaphragms (with spermicide), and cap

		Category		
Condition	Condom	Spermicide	Diaphragm (with spermicide)/Cap	
Known thrombogenic mutations (e.g., factor V Leiden; prothrombin mutation; or protein S, protein C, and antithrombin deficiencies)	1	1	1	Clarification: Routine screening is not appropriate because of the rarity of the conditions and the high cost of screening.
This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).				
Superficial venous disorders	_			
a. Varicose veins     b. Superficial venous thrombosis (acute or history)	1 1	1 1	1 1	_
Current and history of ischemic heart disease This condition is associated with increased risk for adverse	1	1	1	_
health events as a result of pregnancy (Box 2).  Stroke (history of cerebrovascular accident)  This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1	1	1	_
Valvular heart disease Complicated valvular heart disease is associated with increased risk for adverse health events as a result of pregnancy (Box 2).				
a. Uncomplicated	1	1	1	_
b. Complicated (pulmonary hypertension, risk for atrial fibrillation, or history of subacute bacterial endocarditis)	1	1	2	_
Peripartum cardiomyopathy This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2). a. Normal or mildly impaired cardiac function (New York Heart Association Functional Class I or II: patients with no limitation of activities or patients with slight, mild				
limitation of activity) (1) i. <6 months	1	1	1	_
ii. ≥6 months	1	1	1	_
b. Moderately or severely impaired cardiac function (New York Heart Association Functional Class III or IV: patients with marked limitation of activity or patients who should be at complete rest) (1)	1	1	1	_
Rheumatic Diseases Systemic lupus erythematosus This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).				
a. Positive (or unknown) antiphospholipid antibodies	1	1	1	_
b. Severe thrombocytopenia c. Immunosuppressive therapy	1 1	1 1	1 1	_
d. None of the above  Rheumatoid arthritis	1	1	1	_
a. Receiving immunosuppressive therapy b. Not receiving immunosuppressive therapy	1 1	1 1	1 1	_ _
Neurologic Conditions Headaches				_
a. Nonmigraine (mild or severe) b. Migraine	1	1	1	_
i. Without aura (This category of migraine includes menstrual migraine.)	1	1	1	Comment: Menstrual migraine is a subtype of migraine without aura. For more information see <i>The Internationa Headache Society Classification, 3rd edition</i> (http://www.ihs-classification.org/_downloads/mixed/International-Headache-Classification-III-ICHD-III-2013-Beta.pdf).
ii. With aura	1	1	1	_
<b>Epilepsy</b> This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2). <b>Multiple sclerosis</b>	1	1	1	_
a. With prolonged immobility	1	1 1	1	_
b. Without prolonged immobility  Depressive Disorders	1	•	1	_
Depressive disorders Reproductive Tract Infections and Disorders	1	1	1	_
Unexplained vaginal bleeding (suspicious for serious condition) before evaluation	1	1	1	<b>Clarification:</b> If pregnancy or an underlying pathological condition (e.g., pelvic malignancy) is suspected, it must be evaluated and the category adjusted after evaluation

TABLE E1. (Continued) Classifications for barrier methods, including condoms, spermicides, diaphragms (with spermicide), and cap

		Category			
Condition	Condom	Spermicide	Diaphragm (with spermicide)/Cap		
Endometriosis	1	1	1	<u> </u>	
Benign ovarian tumors (including cysts)	1	1	1	_	
Severe dysmenorrhea	1	1	1	_	
Gestational trophoblastic disease					
This condition is associated with increased risk for adverse					
health events as a result of pregnancy (Box 2).  a. Suspected gestational trophoblastic disease					
(immediate postevacuation)					
i. Uterine size first trimester	1	1	1	_	
ii. Uterine size second trimester	1	1	1	_	
b. Confirmed gestational trophoblastic disease	•	·	·		
(after initial evacuation and during monitoring)					
i. Undetectable/nonpregnant β–hCG levels	1	1	1	_	
ii. Decreasing β–hCG levels	1	1	1	_	
iii. Persistently elevated β-hCG levels or malignant disease, with no evidence or suspicion of intrauterine disease	1	1	1	_	
iv. Persistently elevated β-hCG levels or malignant disease, with evidence or suspicion of intrauterine	1	1	1	_	
disease					
Cervical ectropion	1	1	1	_	
Cervical intraepithelial neoplasia	1	1	1	<b>Clarification:</b> The cap should not be used. Diaphragm use has no restrictions.	
Cervical cancer (awaiting treatment)	1	2	1	<b>Clarification:</b> The cap should not be used. Diaphragm use has no restrictions.	
				Comment: Repeated and high-dose use of the spermicide nonoxynol-9 can cause vaginal and cervical irritation or abrasions.	
Breast disease					
Breast cancer is associated with increased risk for adverse health events as a result of pregnancy (Box 2).					
a. Undiagnosed mass	1	1	1	_	
b. Benign breast disease	1	1	1	_	
c. Family history of cancer	1	1	1	_	
d. Breast cancer	_				
i. Current	1	1	1	_	
ii. Past and no evidence of current disease for 5 years	1	1	1	_	
Endometrial hyperplasia	1	1	1	_	
Endometrial cancer This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1	1	1	_	
Ovarian cancer	1	1	1	_	
This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).					
Uterine fibroids	1	1	1		
Anatomical abnormalities	1	1	NA	<b>Clarification:</b> The diaphragm cannot be used in certain cases of prolapse. Cap use is not appropriate for a womar with markedly distorted cervical anatomy.	
Pelvic inflammatory disease a. Past PID					
i. With subsequent pregnancy	1	1	1	_	
ii. Without subsequent pregnancy b. Current PID	1 1	1 1	1 1		
Sexually transmitted diseases  a. Current purulent cervicitis or chlamydial infection or gonococcal infection	1	1	1	_	
b. Vaginitis (including <i>Trichomonas vaginalis</i> and bacterial vaginosis)	1	1	1	_	
c. Other factors related to STDs	1	1	1	_	
HIV					
High risk for HIV	1	4	4	<b>Evidence:</b> Repeated and high-dose use of the spermicide nonoxynol-9 was associated with increased risk for genital lesions, which might increase the risk for HIV infection (2).	
				<b>Comment:</b> Diaphragm use is assigned category 4 because of concerns about the spermicide, not the diaphragm.	

TABLE E1. (Continued) Classifications for barrier methods, including condoms, spermicides, diaphragms (with spermicide), and cap

		Category			
- Condition	Condom	Spermicide	Diaphragm (with spermicide)/Cap	<ul> <li>Clarifications/Evidence/Comments</li> </ul>	
HIV infection For women with HIV infection who are not clinically well or not receiving ARV therapy, this condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1	3	3	Comment: Use of spermicides or diaphragms (with spermicide) can disrupt the cervical mucosa, which migh increase viral shedding and HIV transmission to noninfected sex partners.	
Other Infections Schistosomiasis Schistosomiasis with fibrosis of the liver is associated with increased risk for adverse health events as a result of pregnancy (Box 2).					
a. Uncomplicated	1	1	1	_	
b. Fibrosis of the liver	1	1	1	_	
<b>Tuberculosis</b> This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).					
a. Nonpelvic	1	1	1	_	
b. Pelvic	1	1	1	_	
Malaria	1	1	1	_	
History of toxic shock syndrome	1	1	3	<b>Comment:</b> Toxic shock syndrome has been reported in association with contraceptive sponge and diaphragm use	
Urinary tract infection	1	1	2	<b>Comment:</b> Use of diaphragms and spermicides might increase risk for urinary tract infection.	
Endocrine Conditions Diabetes Insulin-dependent diabetes; diabetes with nephropathy, retinopathy, or neuropathy; diabetes with other vascular disease; or diabetes of >20 years' duration are associated with increased risk for adverse health events as a result of					
pregnancy (Box 2). a. History of gestational disease	1	1	1	_	
b. Nonvascular disease i. Non-insulin dependent	1	1	1	_	
ii. Insulin dependent c. Nephropathy, retinopathy, or neuropathy d. Other vascular disease or diabetes of >20 years' duration	1 1 1	1 1 1	1 1 1	_ _ _	
Thyroid disorders					
a. Simple goiter	1	1	1	_	
b. Hyperthyroid	1	1	1	_	
c. Hypothyroid	1	1	1	_	
Gastrointestinal Conditions Inflammatory bowel disease	1	1	1	_	
(ulcerative colitis or Crohn's disease) <b>Gallbladder disease</b> 2. Symptomatic					
a. Symptomatic i. Treated by cholecystectomy	1	1	1		
	1	1	1	_	
ii. Medically treated iii. Current	1	1	1	<del>-</del>	
b. Asymptomatic	1	1	1	_	
History of cholestasis	ı	I	ı	<del>_</del>	
a. Pregnancy related	1	1	1	_	
b. Past COC related  Viral hepatitis	1	1	1		
a. Acute or flare	1	1	1	_	
b. Carrier	1	1	1	_	
c. Chronic	1	1	1	_	
Cirrhosis		•	•		
Severe cirrhosis is associated with increased risk for adverse health events as a result of pregnancy (Box 2).					
	1	1	1	<u> </u>	
a. Mild (compensated) b. Severe (decompensated)	1	1	1		

TABLE E1. (Continued) Classifications for barrier methods, including condoms, spermicides, diaphragms (with spermicide), and cap

		Category			
Condition			Diaphragm (with spermicide)/Cap	Clarifications/Evidence/Comments	
Liver tumors					
Hepatocellular adenoma and malignant liver tumors are associated with increased risk for adverse health events as a result of pregnancy (Box 2).  a. Benign					
i. Focal nodular hyperplasia	1	1	1	_	
ii. Hepatocellular adenoma	1	1	1	_	
b. Malignant (hepatoma)	1	1	1	_	
Respiratory Conditions					
Cystic fibrosis	1	1	1	_	
This condition is associated with increased risk for adverse					
health events as a result of pregnancy (Box 2).					
Anemias					
Thalassemia	1	1	1	_	
Sickle cell disease	1	1	1	_	
This condition is associated with increased risk for adverse					
health events as a result of pregnancy (Box 2).					
Iron deficiency anemia	1	1	1	_	
Solid Organ Transplantation Solid organ transplantation This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).					
<ul> <li>a. Complicated: graft failure (acute or chronic), rejection, or cardiac allograft vasculopathy</li> </ul>	1	1	1	<del>-</del>	
b. Uncomplicated	1	1	1	_	
	•	·			
Drug Interactions			_	larification: No drug interaction between ARV therapy	
Antiretroviral therapy a. Nucleoside reverse transcriptase inhibitors (NRTIs)				nd barrier method use is known. However, HIV infection	
i. Abacavir (ABC)	1	3		classified as category 3 for spermicides and diaphragm	
ii. Tenofovir (TDF)	1	3		see HIV section).	
iii. Zidovudine (AZT)	1	3	3	•	
iv. Lamivudine (3TC)	1	3	3		
v. Didanosine (DDI)	1	3	3		
vi. Emtricitabine (FTC)	1	3	3		
vii. Stavudine (D4T)	1	3	3		
b. Nonnucleoside reverse transcriptase inhibitors (NNRTIs)					
i. Efavirenz (EFV)	1	3	3		
ii. Etravirine (ETR)	1	3	3		
iii. Nevirapine (NVP)	1	3	3		
iv. Rilpivirine (RPV)	1	3	3		
c. Ritonavir-boosted protease inhibitors					
i. Ritonavir-boosted atazanavir (ATV/r)	1	3	3		
ii. Ritonavir-boosted darunavir (DRV/r)	1	3	3		
iii. Ritonavir-boosted fosamprenavir (FPV/r)	1	3	3		
iv. Ritonavir-boosted lopinavir (LPV/r)	1	3	3		
v. Ritonavir-boosted saquinavir (SQV/r)	1	3 3	3 3		
vi. Ritonavir-boosted tipranavir (TPV/r) d. Protease inhibitors without ritonavir	į.	3	3		
i. Atazanavir (ATV)	1	3	3		
ii. Fosamprenavir (FPV)	1	3	3		
iii. Indinavir (IDV)	1	3	3		
iv. Nelfinavir (NFV)	1	3	3		
e. CCR5 co-receptor antagonists	•	-	-		
i. Maraviroc (MVC)	1	3	3		
f. HIV integrase strand transfer inhibitors					
i. Raltegravir (RAL)	1	3	3		
ii. Dolutegravir (DTG)	1	3	3		
iii. Elvitegravir (EVG)	1	3	3		
g. Fusion inhibitors					
i. Enfuvirtide	1	3	3		
Anticonvulsant therapy	1	4	4		
a. Certain anticonvulsants (phenytoin, carbamazepine,	1	1	1	_	
barbiturates, primidone, topiramate, or oxcarbazepine) b. Lamotrigine	1	1	1	_	
5. Lamourgine	!	1	į.		

TABLE E1. (Continued) Classifications for barrier methods, including condoms, spermicides, diaphragms (with spermicide), and cap

		Category			
Condition	Condom	Condom Spermicide		- Clarifications/Evidence/Comments	
Antimicrobial therapy					
a. Broad-spectrum antibiotics	1	1	1	_	
b. Antifungals	1	1	1	_	
c. Antiparasitics	1	1	1	_	
d. Rifampin or rifabutin therapy	1	1	1	_	
Psychotropic medications					
a. SSRIs	1	1	1	_	
St. John's wort	1	1	1	_	
Allergy to latex	3	1	3	<b>Clarification:</b> The condition of allergy to latex does not apply to plastic condoms/diaphragms.	

**Abbreviations:** ARV = antiretroviral; BMI = body mass index; COC = combined oral contraceptive; DVT = deep venous thrombosis; hCG = human chorionic gonadotropin; HDL = high-density lipoprotein; HIV = human immunodeficiency virus; LDL = low-density lipoprotein; NA = not applicable; PE = pulmonary embolism; PID = pelvic inflammatory disease; SSRI = selective serotonin reuptake inhibitor; STD = sexually transmitted disease.

### References

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# **Appendix F**

# Classifications for Fertility Awareness-Based Methods

Fertility awareness—based (FAB) methods of family planning involve identifying the fertile days of the menstrual cycle, whether by observing fertility signs such as cervical secretions and basal body temperature or by monitoring cycle days (Box F1) (Table F1). FAB methods can be used in combination with abstinence or barrier methods during the fertile time. If barrier methods are used, see the Classifications for Barrier Methods (Appendix E).

No medical conditions worsen because of FAB methods. In general, FAB methods can be used without concern for health effects in persons who choose them. However, several conditions make their use more complex. The existence of these conditions suggests that 1) use of these methods should be delayed until the condition is corrected or resolved, or 2) persons using FAB methods need special counseling, and a provider with particular training in use of these methods is generally necessary to ensure correct use.

Women with conditions that make pregnancy an unacceptable risk should be advised that FAB methods might not be appropriate for them because of the relatively higher typical-use failure rates of these methods. Symptoms-based and calendar-based methods do not protect against sexually transmitted diseases (STDs), including human immunodeficiency virus (HIV), and women using these methods should be counseled that consistent and correct use of the male latex condom reduces the risk for transmission of HIV and other STDs. Use of female condoms can provide protection from transmission of STDs, although data are limited.

BOX F1. Definitions for terms associated with fertility awareness-based methods

- **Symptoms-based methods:** FAB methods based on observation of fertility signs (e.g., cervical secretions or basal body temperature) such as the cervical mucus method, the symptothermal method, and the TwoDay method.
- Calendar-based methods: FAB methods based on calendar calculations such as the calendar rhythm method and the standard days method.
- **Accept:** No medical reason exists to deny the particular FAB method to a woman in this circumstance.
- **Caution:** The method normally is provided in a routine setting but with extra preparation and precautions. For FAB methods, this usually means that special counseling might be needed to ensure correct use of the method by a woman in this circumstance.
- **Delay:** Use of this method should be delayed until the condition is evaluated or corrected. Alternative temporary methods of contraception should be offered.

**Abbreviation:** FAB = fertility awareness—based.

TABLE F1. Fertility awareness-based methods, including symptoms-based and calendar-based methods

	Cate	gory	
Condition	Symptoms-based method	Calendar-based method	— Clarifications/Evidence/Comments
Personal Characteristics and Reprodu Pregnancy	ctive History NA	NA	Clarification: FAB methods are not relevant during pregnancy.
Life stage a. Postmenarche	Caution	Caution	<b>Comment:</b> Menstrual irregularities are common in postmenarche and perimenopause and might complicate the use of FAB methods.
b. Perimenopause Breastfeeding	Caution	Caution	<b>Comment:</b> Use of FAB methods when breastfeeding might be less effective than when not breastfeeding.
a. <6 weeks postpartum b. ≥6 weeks	Delay Caution	Delay Delay	Comment: Women who are primarily breastfeeding and are amenorrheic are unlikely to have sufficient ovarian function to produce detectable fertility signs and hormonal changes during the first 6 months postpartum. However, the likelihood of resumption of fertility increases with time postpartum and with substitution of breast milk by other foods.
c. After menses begin	Caution	Caution	Clarification: When the woman notices fertility signs, particularly cervical secretions, she can use a symptoms-based method. First postpartum menstrual cycles in breastfeeding women vary significantly in length. Return to regularity takes several cycles. When she has had at least three postpartum menses and her cycles are regular again, she can use a calendar-based method. When she has had at least four postpartum menses and her most recent cycle lasted 26–32 days, she can use the standard days method. Before that time, a barrier method should be offered if the woman plans to use a FAB method later.
Postpartum (nonbreastfeeding women)	0.1	6.1	
a. <4 weeks	Delay	Delay	Clarification: Nonbreastfeeding women are not likely to have detectable fertility signs or hormonal changes before 4 weeks postpartum. Although the risk for pregnancy is low, ovulation before first menses is common; therefore, a method appropriate for the postpartum period should be offered.
b. ≥4 weeks	Accept	Delay	Clarification: Nonbreastfeeding women are likely to have sufficient ovarian function to produce detectable fertility signs, hormonal changes, or both at this time; likelihood increases rapidly with time postpartum. Women can use calendar-based methods as soon as they have completed three postpartum menses. Methods appropriate for the postpartum period should be offered before that time.
Postabortion	Caution	Delay	Clarification: After abortion, women are likely to have sufficient ovarian function to produce detectable fertility signs, hormonal changes, or both; likelihood increases with time postabortion. Women can start using calendar-based methods after they have had at least one postabortion menses (e.g., women who before this pregnancy primarily had cycles of 26–32 days can then use the standard days method). Methods appropriate for the postabortion period should be offered before that time.
Reproductive Tract Infections and Dis	orders		
Irregular vaginal bleeding	Delay	Delay	<b>Clarification:</b> Presence of this condition makes FAB methods unreliable. Therefore, barrier methods should be recommended until the bleeding pattern is compatible with proper method use. The condition should be evaluated and treated as necessary.
Vaginal discharge	Delay	Accept	Clarification: Because vaginal discharge makes recognition of cervical secretions difficult, the condition should be evaluated and treated if needed before providing methods based on cervical secretions.
Other			
Use of drugs that affect cycle regularity, hormones, or fertility signs	Caution /Delay	Caution/Delay	Clarification: Use of certain mood-altering drugs such as lithium, tricyclic antidepressants, and antianxiety therapies, as well as certain antibiotics and anti-inflammatory drugs, might alter cycle regularity or affect fertility signs. The condition should be carefully evaluated and a barrier method offered until the degree of effect has been determined or the drug is no longer being used.
Diseases that elevate body temperature a. Chronic diseases	Caution	Accept	Clarification: Elevated temperatures might make basal body temperature difficult to interpret
b. Acute diseases	Delay	Accept	but have no effect on cervical secretions. Thus, use of a method that relies on temperature should be delayed until the acute febrile disease abates. Temperature-based methods are not appropriate for women with chronically elevated temperatures. In addition, some chronic diseases interfere with cycle regularity, making calendar-based methods difficult to interpret.

 $\textbf{Abbreviations:} \ \mathsf{FAB} = \mathsf{fertility} \ \mathsf{awareness-based;} \ \mathsf{NA} = \mathsf{not} \ \mathsf{applicable.}$ 

# **Appendix G**

## **Lactational Amenorrhea Method**

The Bellagio Consensus provided the scientific basis for defining the conditions under which breastfeeding can be used safely and effectively for birth-spacing purposes; programmatic guidelines were developed at a meeting of family planning experts for its use as a method of family planning, and the method was then given the name the lactational amenorrhea method (1,2). These guidelines include the following three criteria, all of which must be met to ensure adequate protection from an unplanned pregnancy: 1) amenorrhea; 2) fully or nearly fully breastfeeding (no interval of >4–6 hours between breastfeeds); and 3) <6 months postpartum.

All major medical organizations recommend exclusive breastfeeding for the first 6 months of life, with continuing breastfeeding through the first year and beyond for as long as mutually desired (3). No medical conditions exist for which use of the lactational amenorrhea method for contraception is restricted. However, breastfeeding might not be recommended for women or infants with certain conditions.

Women with conditions that make pregnancy an unacceptable risk should be advised that the lactational amenorrhea method might not be appropriate for them because of its relatively higher typical-use failure rates. The lactational amenorrhea method does not protect against sexually transmitted diseases (STDs), including human immunodeficiency virus (HIV), and women using this method should be counseled that consistent and correct use of the male latex condom reduces the risk for transmission of HIV and other STDs. Use of female condoms can provide protection from transmission of STDs, although data are limited.

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### **HIV Infection**

HIV can be transmitted from mother to infant through breastfeeding. Therefore, in the United States, where replacement feeding is affordable, feasible, acceptable, sustainable, and safe, breastfeeding for women with HIV is not recommended (3,4).

### **Other Medical Conditions**

The American Academy of Pediatrics (AAP) also recommends against breastfeeding for women with active untreated tuberculosis disease, untreated brucellosis, varicella, H1N1 influenza, or positivity for human T-cell lymphotropic virus types I or II or for those who have herpes simplex lesions on a breast. In addition, infants with classic galactosemia should not breastfeed (3).

## **Medication Used During Breastfeeding**

AAP recommends that the benefits of breastfeeding outweigh the risk of exposure to most therapeutic agents via human milk. More information about specific drugs and radioactive compounds is provided by AAP (5) and LactMed (http://toxnet.nlm.nih.gov).

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# **Appendix H**

## **Coitus Interruptus (Withdrawal)**

Coitus interruptus, also known as withdrawal, is a traditional family planning method in which the man completely removes his penis from the vagina and away from the external genitalia of the female partner before he ejaculates. Coitus interruptus prevents sperm from entering the woman's vagina, thereby preventing contact between spermatozoa and the ovum. This method might be appropriate for couples

- who are highly motivated and able to use this method effectively;
- with religious or philosophical reasons for not using other methods of contraception;
- who need contraception immediately and have entered into a sexual act without alternative methods available;
- who need a temporary method while awaiting the start of another method; or
- who have intercourse infrequently.

Some benefits of coitus interruptus are that the method, if used correctly, does not affect breastfeeding and is always available for primary use or use as a back-up method. In addition, coitus interruptus involves no economic cost or use of chemicals and has no directly associated health risks. Coitus interruptus does not protect against sexually transmitted diseases (STDs), including human immunodeficiency virus (HIV), and women using this method should be counseled that consistent and correct use of the male latex condom reduces the risk for transmission of HIV and other STDs. Use of female condoms can provide protection from transmission of STDs, although data are limited.

Coitus interruptus is unforgiving of incorrect use, and its effectiveness depends on the willingness and ability of the couple to use withdrawal with every act of intercourse. Women with conditions that make pregnancy an unacceptable risk should be advised that coitus interruptus might not be appropriate for them because of its relatively higher typical-use failure rates.

# **Appendix I**

### **Female and Male Sterilization**

Tubal sterilization for women and vasectomy for men are permanent, safe, and highly effective methods of contraception. In general, no medical conditions absolutely restrict a person's eligibility for sterilization (with the exception of known allergy or hypersensitivity to any materials used to complete the sterilization method). However, certain conditions place a woman at high surgical risk; in these cases, careful consideration should be given to the risks and benefits of other acceptable alternatives, including long-acting, highly effective, reversible methods and vasectomy. Female and male sterilization do not protect against sexually transmitted diseases (STDs), including human immunodeficiency virus (HIV), and women using these methods should be counseled that consistent and correct use of the male latex condom reduces the risk for transmission of HIV and other STDs. Use of female condoms can provide protection from transmission of STDs, although data are limited.

Because these methods are intended to be irreversible, persons who choose sterilization should be certain that they want to prevent pregnancy permanently. Most persons who choose sterilization remain satisfied with their decision. However, a small proportion of women regret this decision (1%-26%) from different studies, with higher rates of regret reported by women who were younger at sterilization) (1,2). Regret among men about vasectomy has been reported to be approximately 5% (3), similar to the proportion of women who report regretting their husbands' vasectomy (6%) (4). Therefore, all persons should be appropriately counseled about the permanency of sterilization and the availability of highly effective, reversible methods of contraception.

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# **Appendix J**

## **Classifications for Emergency Contraception**

A copper-containing intrauterine device (Cu-IUD) can be used within 5 days of unprotected intercourse as an emergency contraceptive. However, when the time of ovulation can be estimated, the Cu-IUD can be inserted beyond 5 days after intercourse, if necessary, as long as the insertion does not occur >5 days after ovulation. The eligibility criteria for interval Cu-IUD insertion also apply for the insertion of Cu-IUDs as emergency contraception (Box J1) (Table J1).

Classifications for emergency contraceptive pills (ECPs) are given for ulipristal acetate (UPA), levonorgestrel (LNG), and combined oral contraceptives (COCs). Cu-IUDs, UPA, LNG, and COCs do not protect against sexually transmitted diseases (STDs), including human immunodeficiency virus (HIV), and women using these methods should be counseled that consistent and correct use of the male latex condom reduces

### BOX J1. Categories for classifying emergency contraception

- 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.

the risk for transmission of HIV and other STDs. Use of female condoms can provide protection from transmission of STDs, although data are limited.

TABLE J1. Classifications for emergency contraception, including the copper-containing intrauterine device, ulipristal acetate, levonorgestrel, and combined oral contraceptives\*

		Cate	gory		
Condition	Cu-IUD	UPA	LNG	coc	Clarifications/Evidence/Comments
Personal Characteristics and Reproductive Hist	ory				
Pregnancy	4	NA	NA	NA	Clarification (IUD): The IUD is not indicated during pregnancy and should not be used because of the risk for serious pelvic infection and septic spontaneous abortion.
					Clarification (ECPs): Although this method is not indicated for a woman with a known or suspected pregnancy, no harm to the woman, the course of her pregnancy, or the fetus if ECPs are inadvertently used is known to exist.
					<b>Evidence:</b> Evidence suggests that poor pregnancy outcomes are rare among pregnant women who used ECPs during conception cycle or early ir pregnancy (1).
Breastfeeding	1	1	1	1	Clarification (UPA): Breastfeeding is not recommended for 24 hours after taking UPA because it is excreted in breast milk, with highest concentrations in the first 24 hours, and maximum maternal serum levels are reached 1–3 hours after administration. Mean UPA concentrations in breast milk decrease markedly from 0 to 24–48 hours and then slowly decrease over 5 days (2). Breast milk should be expressed and discarded for 24 hours after taking UPA.
					<b>Evidence:</b> Breastfeeding outcomes do not seem to differ between women exposed to LNG and those who are not exposed. One pharmacokinetic study demonstrated that LNG passes to breast milk but in minimal quantities (1).
Past ectopic pregnancy History of bariatric surgery This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1	1	1	1	_
a. Restrictive procedures: decrease storage capacity of the stomach (vertical banded gastroplasty, laparoscopic adjustable gastric band, or laparoscopic sleeve gastrectomy)	1	1	1	1	_
b. Malabsorptive procedures: decrease absorption of nutrients and calories by shortening the functional length of the small intestine (Roux-en-Y gastric bypass or biliopancreatic diversion)	1	1	1	1	Comment: Bariatric surgical procedures involving a malabsorptive component have the potential to decrease oral contraceptive effectiveness perhaps further decreased by postoperative complications such as long-term diarrhea, vomiting, or both. Because of these malabsorptive concerns, an emergency IUD might be more appropriate than ECPs.

TABLE J1. (Continued) Classifications for emergency contraception, including the copper-containing intrauterine device, ulipristal acetate, levonorgestrel, and combined oral contraceptives\*

_	Category						
Condition	Cu-IUD	UPA	LNG	coc	Clarifications/Evidence/Comments		
Cardiovascular Disease							
History of severe cardiovascular disease (ischemic heart disease, cerebrovascular attack, or other thromboembolic conditions) This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	1	2	2	2	<b>Comment:</b> The duration of ECP use is less than that of regular use of COCs or POPs and thus would be expected to have less clinical impact.		
Rheumatic Diseases Rheumatoid arthritis							
a. Receiving immunosuppressive therapy     b. Not receiving immunosuppressive therapy	2 1	1 1	1 1	1 1	=		
Neurologic Conditions Migraine	1	1	1	2	<b>Comment:</b> The duration of ECP use is less than that of regular use of COCs and thus would be expected to have less clinical impact.		
Gastrointestinal Conditions Inflammatory bowel disease (ulcerative colitis or Crohn's disease)	1	1	1	1	_		
Severe liver disease (including jaundice)	1	2	2	2	Comment: The duration of ECP use is less than that of regular use of COCs		
This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).					or POPs and thus would be expected to have less clinical impact.		
Solid Organ Transplantation Solid organ transplantation This condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).							
a. Complicated: graft failure (acute or chronic), rejection, or cardiac allograft vasculopathy	3	1	1	1	_		
b. Uncomplicated Other	2	1	1	1	<del>-</del>		
Repeated ECP use	1	1	1	1	Clarification: Recurrent ECP use is an indication that the woman requires further counseling about other contraceptive options. Frequently repeated ECP use might be harmful for women with conditions classified as 2, 3, or 4 for CHC or POC use.		
					<b>Evidence:</b> In one case-control study, risk for ectopic pregnancy compared with intrauterine pregnancy did not increase after repeated use of LNG ECPs compared with nonuse (1).		
Sexual assault	2	1	1	1	Clarification (IUD): Women who have experienced sexual assault are at increased risk for STDs. According to CDC STD treatment guidelines, routing presumptive treatment of chlamydia, gonorrhea, and trichomonas is recommended after sexual assault (3). Women with current purulent cervicitis or chlamydial infection or gonococcal infection should not undergo IUD insertion (category 4).		
Obesity (BMI ≥30 kg/m²)	1	2	2	2	Clarification (ECPs): ECPs might be less effective among women with BMI ≥30 kg/m² than among women with BMI <25 kg/m². Despite this, no safety concerns exist.		
					Evidence: Limited evidence from secondary data analyses suggests that women with BMI ≥30 kg/m² experience an increased risk for pregnancy after use of LNG compared with women with BMI <25 kg/m². Two analyses suggest obese women might also experience an increased risk for pregnancy after use of UPA compared with nonobese women, although this increase was not significant in one study (4).		
CYP3A4 inducers (e.g., bosentan, carbamazepine, felbamate, griseofulvin, oxcarbazepine, phenytoin,	1	2	2	2	<b>Clarification (ECPs):</b> Strong CYP3A4 inducers might reduce the effectiveness of ECPs.		
ifampin, St. John's wort, topiramate, efavirenz, and umacaftor)					Evidence: According to labelling information, rifampin markedly decreases UPA levels by ≥90%, which might decrease its efficacy (2). Therefore, theoretical concerns extend to use of other CYP3A4 inducers as well as to COC and LNG ECPs, which have metabolic pathways similar to those of UP/A small pharmacokinetic study found that concomitant efavirenz use decreased LNG levels in women taking LNG ECPs (0.75 mg) by 56% compared with LNG ECPs alone (5).		

Abbreviations: BMI = body mass index; CHC = combined hormonal contraceptive; COC = combined hormonal contraceptive; CU-IUD = copper-containing intrauterine device; ECP = emergency contraceptive pill; HIV = human immunodeficiency virus; IUD = intrauterine device; LNG = levonorgestrel; NA = not applicable; POC = progestin-only contraceptive; POP = progestin-only pill; STD = sexually transmitted disease; UPA = ulipristal acetate.

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# **Appendix K**

# Summary of Classifications for Hormonal Contraceptive Methods and Intrauterine Devices

Health-care providers can use the summary table as a quick reference guide to the classifications for hormonal contraceptive methods and intrauterine contraception to compare classifications across these methods (Box K1) (Table K1). See the respective appendix for each method for clarifications to the numeric categories, as well as for summaries of the evidence and additional comments. Hormonal contraceptives and intrauterine devices do not protect against sexually transmitted diseases (STDs), including human immunodeficiency virus (HIV), and women using these methods should be counseled that consistent and correct use of the male latex condom reduces the risk for transmission of HIV and other STDs. Use of female condoms can provide protection from transmission of STDs, although data are limited.

BOX K1. Categories for classifying hormonal contraceptives and intrauterine devices

- 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.

TABLE K1. Summary of classifications for hormonal contraceptive methods and intrauterine devices

Condition	Cu-IUD	LNG-IUD	Implants	DMPA	POP	CHCs
Personal Characteristics And Repro	ductive History					
Pregnancy	4*	4*	NA*	NA*	NA*	NA*
Age	Menarche to	Menarche to	Menarche to	Menarche to	Menarche to	Menarche to
,	<20 years: 2	<20 years: 2	<18 years: 1	<18 years: 2	<18 years: 1	<40 years: 1
	≥20 years: 1	≥20 years: 1	18-45 years: 1	18-45 years: 1	18–45 years: 1	≥40 years: 2
	•	•	>45 years: 1	>45 years: 2	>45 years: 1	•
Parity				•		
a. Nulliparous	2	2	1	1	1	1
b. Parous	1	1	1	1	1	1
Breastfeeding						
a. <21 days postpartum	_	_	2*	2*	2*	4*
b. 21 to <30 days postpartum						
i. With other risk factors for VTE (e.g., age ≥35 years, previous VTE, thrombophilia, immobility, transfusion at delivery, peripartum cardiomyopathy, BMI ≥30 kg/m², postpartum hemorrhage,	_	_	2*	2*	2*	3*
postcesarean delivery, preeclampsia, or smoking)						
ii. Without other risk factors for VTE	_	_	2*	2*	2*	3*
c. 30–42 days postpartum			-	-	-	,
i. With other risk factors for VTE (e.g., age ≥35 years, previous VTE, thrombophilia, immobility, transfusion at delivery, peripartum cardiomyopathy, BMI ≥30 kg/m², postpartum hemorrhage, postcesarean delivery, preeclampsia,	_	_	1*	1*	1*	3*
or smoking)			- 4	- "	- "	- "
ii. Without other risk factors for VTE	_	_	1*	1*	1*	2*
d. >42 days postpartum	_	_	1*	1*	1*	2*

TABLE K1. (Continued) Summary of classifications for hormonal contraceptive methods and intrauterine devices

Condition	Cu-IUD	LNG-IUD	Implants	DMPA	POP	CHCs
Postpartum (nonbreastfeeding						
women)			1	1	1	4
a. <21 days postpartum b. 21–42 days postpartum	_	_	1	1	1	4
i. With other risk factors for VTE (e.g.,	_	_	1	1	1	3*
age ≥35 years, previous VTE,			'	'	'	3
thrombophilia, immobility,						
transfusion at delivery, peripartum						
cardiomyopathy, BMI ≥30 kg/m²,						
postpartum hemorrhage, postcesarean delivery, preeclampsia,						
or smoking)						
ii. Without other risk factors for VTE	_	_	1	1	1	2
c. >42 days postpartum	_	_	1	1	1	1
Postpartum (including cesarean						
delivery)						
a. <10 minutes after delivery of the placenta						
i. Breastfeeding	1*	2*	_	_	_	_
ii. Nonbreastfeeding	1*	1*	_			
b. 10 minutes after delivery of the	2*	2*	_	_	_	_
placenta to <4 weeks (breastfeeding						
or nonbreastfeeding)						
c. ≥4 weeks (breastfeeding or	1*	1*	_	_	_	_
nonbreastfeeding)	4	4				
d. Postpartum sepsis  Postabortion	4	4	_	_	_	_
a. First trimester	1*	1*	1*	1*	1*	1*
b. Second trimester	2*	2*	1*	1*	1*	1*
c. Immediate postseptic abortion	4	4	1*	1*	1*	1*
Past ectopic pregnancy	1	1	1	1	2	1
History of pelvic surgery (see	1	1	1	1	1	1
Postpartum [Including Cesarean						
Delivery] section)						
Smoking a. Age <35 years	1	1	1	1	1	2
b. Age ≥35 years	1	ı	ı	'	1	2
i. <15 cigarettes per day	1	1	1	1	1	3
ii. ≥15 cigarettes per day	1	1	1	1	1	4
Obesity						
a. BMI ≥30 kg/m <sup>2</sup>	1	1	1	1	1	2
b. Menarche to <18 years and BMI	1	1	1	2	1	2
≥30 kg/m <sup>2</sup>						
History of bariatric surgery This condition is associated with						
increased risk for adverse health events						
as a result of pregnancy (Box 2).						
a. Restrictive procedures: decrease	1	1	1	1	1	1
storage capacity of the stomach (vertical banded gastroplasty,						
laparoscopic adjustable gastric band,						
or laparoscopic sleeve gastrectomy)						
b. Malabsorptive procedures:	1	1	1	1	3	COCs: 3
decrease absorption of nutrients and						
calories by shortening the functional						Patch and ring: 1
length of the small intestine (Roux-en-Y gastric bypass or						
biliopancreatic diversion)						
Cardiovascular Disease						
Multiple risk factors for atherosclerotic	1	2	2*	3*	2*	3/4*
cardiovascular disease (e.g., older age,						
smoking, diabetes, hypertension, low						
HDL, high LDL, or high triglyceride levels)						
Hypertension						
Systolic blood pressure ≥160 mm Hg or diastolic blood pressure ≥100 mm Hg						
are associated with increased risk for						
adverse health events as a result of						
pregnancy (Box 2).						
a. Adequately controlled	1*	1*	1*	2*	1*	3*
hypertension						

TABLE K1. (Continued) Summary of classifications for hormonal contraceptive methods and intrauterine devices

Condition	Cu-IUD	LNG-IUD	Implants	DMPA	POP	CHCs
b. Elevated blood pressure levels						
(properly taken measurements)						
i. Systolic 140–159 mm Hg or	1*	1*	1*	2*	1*	3*
diastolic 90–99 mm Hg		2 ×	2.4	2.4	2.4	
ii. Systolic ≥160 mm Hg or diastolic ≥100 mm Hg	1*	2*	2*	3*	2*	4*
c. Vascular disease	1*	2*	2*	3*	2*	4*
History of high blood pressure during	1	1	1	1	1	2
pregnancy (when current blood	'	'	ı	'	'	2
pressure is measurable and normal)						
Deep venous thrombosis/						
Pulmonary embolism						
a. History of DVT/PE, not receiving						
anticoagulant therapy	_			_	_	
i. Higher risk for recurrent DVT/PE	1	2	2	2	2	4
<ul><li>(one or more risk factors)</li><li>History of estrogen-associated</li></ul>						
DVT/PE						
Pregnancy-associated DVT/PE						
• Idiopathic DVT/PE						
<ul> <li>Known thrombophilia, including</li> </ul>						
antiphospholipid syndrome						
Active cancer (metastatic,						
receiving therapy, or within 6 months after clinical remission),						
excluding nonmelanoma skin						
cancer						
History of recurrent DVT/PE						
ii. Lower risk for recurrent DVT/PE	1	2	2	2	2	3
(no risk factors)						
b. Acute DVT/PE	2	2	2	2	2	4
c. DVT/PE and established anticoagu-						
lant therapy for at least 3 months	_			_	_	
i. Higher risk for recurrent DVT/PE	2	2	2	2	2	4*
(one or more risk factors)  • Known thrombophilia, including						
antiphospholipid syndrome						
Active cancer (metastatic,						
receiving therapy, or within						
6 months after clinical remission),						
excluding nonmelanoma skin						
cancer						
History of recurrent DVT/PE	2	2	2	2	2	2*
ii. Lower risk for recurrent DVT/PE (no risk factors)	2	2	2	2	2	3*
d. Family history (first-degree	1	1	1	1	1	2
relatives)	·	•	•	·	·	-
e. Major surgery						
i. With prolonged immobilization	1	2	2	2	2	4
ii. Without prolonged	1	1	1	1	1	2
immobilization						
f. Minor surgery without	1	1	1	1	1	1
immobilization	- "		- "	- "		
Known thrombogenic mutations (e.g.,	1*	2*	2*	2*	2*	4*
actor V Leiden; prothrombin mutation; and protein S, protein C, and						
antithrombin deficiencies)						
This condition is associated with						
ncreased risk for adverse health events						
as a result of pregnancy (Box 2).						
Superficial venous disorders						
a. Varicose veins	1	1	1	1	1	1
b. Superficial venous thrombosis	1	1	1	1	1	3*
(acute or history)		Indiana Control	Interest Court of		Initiation Cont	
Current and history of ischemic heart disease	1		Initiation Continuation	2	Initiation Continuation	A
neart disease This condition is associated with	1	2 3	2 3	3	2 3	4
ncreased risk for adverse health events						
as a result of pregnancy (Box 2).						

TABLE K1. (Continued) Summary of classifications for hormonal contraceptive methods and intrauterine devices

Condition	Cu-IUD		LNO	G-IUD	)	Implants	DMF	PA	POP	CHCs
troke (history of cerebrovascular						Initiation Continuation			Initiation Continuation	
ccident)  icreased risk for adverse health events a result of pregnancy (Box 2).  alvular heart disease omplicated valvular heart disease is ssociated with increased risk for diverse health events as a result of	1			2		2 3	3		2 3	4
regnancy (Box 2).	1			1		1	1		1	2
a. Uncomplicated b. Complicated (pulmonary hypertension, risk for atrial fibrillation, or history of subacute bacterial endocarditis)	1			1		1 1	1		1	2 4
reripartum cardiomyopathy his condition is associated with ncreased risk for adverse health events s a result of pregnancy (Box 2). a. Normal or mildly impaired cardiac function (New York Heart Association Functional Class I or II: patients with no limitation of activities or patients with slight, mild limitation of activity) (1)										
i. <6 months	2			2		1	1		1	4
ii. ≥6 months b. Moderately or severely impaired cardiac function (New York Heart Association Functional Class III or IV: patients with marked limitation of activity or patients who should be at complete rest) (1).	2 2			2 2		1 2	1 2		1 2	3 4
heumatic Diseases ystemic lupus erythematosus nis condition is associated with	Initiation Cont	inuation					Initiation C	ontinuatio	on	
ncreased risk for adverse health events s a result of pregnancy (Box 2). a. Positive (or unknown) antiphospho-	1*	1*		3*		3*	3*	3*	3*	4*
lipid antibodies b. Severe thrombocytopenia	3*	2*		2*		2*	3*	2*	2*	2*
c. Immunosuppressive therapy	2*	1*		2*		2*	2*	2*	2*	2*
d. None of the above	1*	1*		2*		2*	2*	2*	2*	2*
heumatoid arthritis a. Receiving immunosuppressive therapy	Initiation Cont 2	inuation 1	2		nuation 1	1	2/3*	÷	1	2
b. Not receiving immunosuppressive therapy	1			1		1	2		1	2
leurologic Conditions leadaches										
a. Nonmigraine (mild or severe) b. Migraine	1			1		1	1		1	1*
i. Without aura (This category of migraine includes menstrual migraine.)	1			1		1	1		1	2*
ii. With aura pilepsy	1 1			1		1 1*	1 1*		1 1*	4* 1*
priepsy his condition is associated with hereased risk for adverse health events s a result of pregnancy (Box 2). fultiple sclerosis	1			•		1	Į.		'	ı
a. With prolonged immobility	1			1		1	2		1	3
b. Without prolonged immobility Depressive Disorders	1			1		1	2		1	1
Pepressive disorders	1*			1*		1*	1*	÷	1*	1*
eproductive Tract Infections and aginal bleeding patterns	Disorders		Initiation	Conti	nuation					
a. Irregular pattern without heavy bleeding	1		1		1	2	2		2	1
b. Heavy or prolonged bleeding (includes regular and irregular patterns)	2*		1*		2*	2*	2*	ŧ	2*	1*

TABLE K1. (Continued) Summary of classifications for hormonal contraceptive methods and intrauterine devices

Condition	Cu	ı-IUD	LN	G-IUD	Implants	DMPA	POP	CHCs
Unexplained vaginal bleeding (suspicious for serious condition)	Initiation 4*	Continuation 2*	Initiation 4*	Continuation 2*	3*	3*	2*	2*
pefore evaluation		2		1	1	1	1	1
Endometriosis		2		1	1	1	1	1
Benign ovarian tumors (including		1		1	1	1	1	1
cysts)		2		1				
Severe dysmenorrhea		2		1	1	1	1	1
Gestational trophoblastic disease								
This condition is associated with ncreased risk for adverse health events as a result of pregnancy (Box 2).								
a. Suspected gestational trophoblastic								
disease (immediate postevacuation)								
i. Uterine size first trimester		1*		1*	1*	1*	1*	1*
ii. Uterine size second trimester		2*		2*	1*	1*	1*	1*
b. Confirmed gestational trophoblastic disease (after initial evacuation and during monitoring)	Initiation	Continuation	Initiation	Continuation				
i. Undetectable/nonpregnant β-hCG levels	1*	1*	1*	1*	1*	1*	1*	1*
ii. Decreasing β-hCG levels	2*	1*	2*	1*	1*	1*	1*	1*
iii. Persistently elevated β-hCG levels		1*	2*	1*	1*	1*	1*	1*
or malignant disease, with no evidence or suspicion of intrauterine disease		·	-	·	·	·	·	·
iv. Persistently elevated β-hCG levels or malignant disease, with evidence	4*	2*	4*	2*	1*	1*	1*	1*
or suspicion of intrauterine disease								
Cervical ectropion		1		1	1	1	1	1
Cervical intraepithelial neoplasia		1		2	2	2	1	2
Cervical intraepitation (Teoplasia	Initiation	Continuation	Initiation		2	2	'	2
cervical carrier (awarting treatment)	4	2	4	2	2	2	1	2
Breast disease	7	2	7	2	2	2	'	2
Breast cancer is associated with increased risk of adverse health events as a result of pregnancy (Box 2).								
a. Undiagnosed mass		1		2	2*	2*	2*	2*
b. Benign breast disease		1		1	1	1	1	1
c. Family history of cancer		1		1	1	1	1	1
d. Breast cancer								
i. Current		1		4	4	4	4	4
ii. Past and no evidence of current		1		3	3	3	3	3
disease for 5 years		•		_	-	-	-	-
Endometrial hyperplasia		1		1	1	1	1	1
Endometrial cancer	Initiation	Continuation	Initiation	Continuation				
This condition is associated with		continuation.		corraradaori				
ncreased risk for adverse health events as a result of pregnancy (Box 2).	4	2	4	2	1	1	1	1
Ovarian cancer		1		1	1	1	1	1
This condition is associated with increased risk for adverse health events								
as a result of pregnancy (Box 2).		2		2	1	1	1	4
Uterine fibroids		2		2	ı	1	1	1
Anatomical abnormalities								
a. Distorted uterine cavity (any congenital or acquired uterine abnormality distorting the uterine		4		4	_	_	_	_
cavity in a manner that is incompatible with IUD insertion)								
		2		2	_	_	_	_
b. Other abnormalities (including cervical stenosis or cervical lacerations) not distorting the uterine cavity or interfering with IUD insertion								
cervical stenosis or cervical lacerations) not distorting the uterine cavity or interfering with IUD insertion								
cervical stenosis or cervical lacerations) not distorting the uterine cavity or interfering with IUD insertion Pelvic inflammatory disease		Continuation	Initiation	Continuation				
cervical stenosis or cervical lacerations) not distorting the uterine cavity or interfering with IUD insertion Pelvic inflammatory disease a. Past PID	Initiation	Continuation	Initiation		1	1	1	1
cervical stenosis or cervical lacerations) not distorting the uterine cavity or interfering with IUD insertion Pelvic inflammatory disease		Continuation 1 2		Continuation 1 2	1 1	1	1 1	1 1

TABLE K1. (Continued) Summary of classifications for hormonal contraceptive methods and intrauterine devices

Condition	Cı	ı-IUD	LNC	G-IUD	Implants	DMPA	POP	CHCs
Sexually transmitted diseases  a. Current purulent cervicitis or chlamydial infection or gonococcal infection	Initiation 4	Continuation 2*	Initiation 4	Continuation 2*	1	1	1	1
b. Vaginitis (including <i>Trichomonas</i> vaginalis and bacterial vaginosis)	2	2	2	2	1	1	1	1
c. Other factors related to STDs	2*	2	2*	2	1	1	1	1
HIV	Initiation	Continuation	Initiation	Continuation				
High risk for HIV	2	2	2	2	1	1*	1	1
HIV infection For women with HIV infection who are not clinically well or not receiving ARV therapy, this condition is associated with increased risk for adverse health events as a result of pregnancy (Box 2).	_	_	_	_	1*	1*	1*	1*
a. Clinically well receiving ARV therapy	1	1	1	1	_	_	_	_
b. Not clinically well or not receiving ARV therapy	2	1	2	1	_	_	_	_
Other Infections Schistosomiasis Schistosomiasis with fibrosis of the liver is associated with increased risk for adverse health events as a result of pregnancy (Box 2). a. Uncomplicated b. Fibrosis of the liver (if severe, see Cirrhosis)		1 1		1	1 1	1 1	1 1	1 1
Tuberculosis This condition is associated with ncreased risk for adverse health events as a result of pregnancy (Box 2).	Initiation	Continuation	Initiation	Continuation				
a. Nonpelvic b. Pelvic	1 4	1 3	1 4	1 3	1* 1*	1* 1*	1* 1*	1* 1*
Malaria	4	1		1	1	1	1	1
Endocrine Conditions Diabetes Insulin-dependent diabetes; diabetes with nephropathy, retinopathy, or neuropathy; diabetes with other vascular disease; or diabetes of >20 years' duration are associated with increased risk of adverse health events as a result of pregnancy (Box 2). a. History of gestational disease		1		1	1	1	1	1
b. Nonvascular disease		1		2	2	2	2	2
i. Non-insulin dependent ii. Insulin dependent		1		2	2 2	2 2	2 2	2 2
c. Nephropathy, retinopathy, or neuropathy		1		2	2	3	2	3/4*
d. Other vascular disease or diabetes of >20 years' duration Thyroid disorders		1		2	2	3	2	3/4*
a. Simple goiter		1		1	1	1	1	1
b. Hyperthyroid		1		1	1	1	1	1
c. Hypothyroid		1		1	1	1	1	1
Gastrointestinal Conditions Inflammatory bowel disease (ulcerative colitis or Crohn's disease) Gallbladder disease a. Symptomatic		1		1	1	2	2	2/3*
i. Treated by cholecystectomy		1		2	2	2	2	2
ii. Medically treated		1		2	2	2	2	3
iii. Current		1		2	2	2	2	3
b. Asymptomatic History of cholestasis		1		2	2	2	2	2
a. Pregnancy related		1		1	1	1	1	2
b. Past COC related		1		2	2	2	2	3

TABLE K1. (Continued) Summary of classifications for hormonal contraceptive methods and intrauterine devices

Condition	Cu-IUD	LNG-IUD	Implants	DMPA	POP	C	HCs
Viral hepatitis						Initiation	Continuation
a. Acute or flare	1	1	1	1	1	3/4*	2
b. Carrier	1	1	1	1	1	1	1
c. Chronic	1	1	1	1	1	1	1
Cirrhosis							
Severe cirrhosis is associated with							
increased risk for adverse health events							
as a result of pregnancy (Box 2).	1	1	1	1	1		1
a. Mild (compensated) b. Severe (decompensated)	1 1	1	3	1 3	3		1
Liver tumors	'	3	3	3	3		4
Hepatocellular adenoma and malignant							
liver tumors are associated with							
increased risk for adverse health events							
as a result of pregnancy (Box 2).							
a. Benign							
i. Focal nodular hyperplasia	1	2	2	2	2		2
ii. Hepatocellular adenoma	1	3	3	3	3		4
b. Malignant (hepatoma)	1	3	3	3	3		4
Respiratory Conditions							
Cystic fibrosis	1*	1*	1*	2*	1*		1*
This condition is associated with							
increased risk for adverse health events as a result of pregnancy (Box 2).							
, , , , , ,							
Anemias			_	_			_
Thalassemia	2	1	1	1	1		1
Sickle cell disease This condition is associated with	2	1	1	1	1		2
increased risk for adverse health events							
as a result of pregnancy (Box 2).							
Iron-deficiency anemia	2	1	1	1	1		1
Solid Organ Transplantation							
Solid organ transplantation	Initiation Continuation	Initiation Contin	uation				
This condition is associated with	midation Continuation	midation contain	addorr				
increased risk for adverse health events							
as a result of pregnancy (Box 2).							
a. Complicated: graft failure (acute or	3 2	3 2	2 2	2	2		4
chronic), rejection, or cardiac allograft							
vasculopathy	2 2	2		2	2		2*
b. Uncomplicated	2 2	2 2	2 2	2	2		2
Drug Interactions							
Antiretroviral therapy	Initiation Continuation	Initiation Contin	uation				
a. Nucleoside reverse transcriptase inhibitors (NRTIs)							
	1/2* 1*	1/2* 1	* 1	1	1		1
i. Abacavir (ABC) ii. Tenofovir (TDF)	1/2* 1*	1/2* 1 1/2* 1		1 1	1		1
iii. Zidovudine (AZT)	1/2* 1*	1/2* 1		1	1		1
iv. Lamivudine (3TC)	1/2* 1*	1/2* 1		1	1		1
v. Didanosine (DDI)	1/2* 1*	1/2* 1		1	1		1
vi. Emtricitabine (FTC)	1/2* 1*	1/2* 1	* 1	1	1		1
vii. Stavudine (D4T)	1/2* 1*	1/2* 1		1	1		1
b. Nonnucleoside reverse transcrip-							
tase inhibitors (NNRTIs)							
i. Efavirenz (EFV)	1/2* 1*	1/2* 1		1*	2*		2*
ii. Etravirine (ETR)	1/2* 1*	1/2* 1		1	1		1
iii. Nevirapine (NVP)	1/2* 1*	1/2* 1		1	1		1
iv. Rilpivirine (RPV)	1/2* 1*	1/2* 1	* 1	1	1		1
c. Ritonavir-boosted protease inhibitors							
i. Ritonavir-boosted atazanavir	1/2* 1*	1/2* 1	* 2*	1*	2*		2*
(ATV/r)	1/2	1/2 1	2	'	2		2
ii. Ritonavir-boosted darunavir	1/2* 1*	1/2* 1	* 2*	1*	2*		2*
(DRV/r)	•		·		-		
iii. Ritonavir-boosted fosamprenavir	1/2* 1*	1/2* 1	* 2*	1*	2*		2*
(FPV/r)							
iv. Ritonavir-boosted lopinavir	1/2* 1*	1/2* 1	* 1	1	1		1
(LPV/r)	1/2*	1/2*	× ~ ~ ~		~*		2*
v. Ritonavir-boosted saquinavir	1/2* 1*	1/2* 1	* 2*	1*	2*		2*
(SQV/r) vi. Ritonavir-boosted tipranavir	1/2* 1*	1/2* 1	* 2*	1*	2*		2*
	1/4	1/∠	∠	I	_		_

TABLE K1. (Continued) Summary of classifications for hormonal contraceptive methods and intrauterine devices

Condition	Cu-	IUD	LNG	-IUD	Implants	DMPA	POP	CHCs
d. Protease inhibitors without								
ritonavir								
i. Atazanavir (ATV)	1/2*	1*	1/2*	1*	1	1	1	2*
ii. Fosamprenavir (FPV)	1/2*	1*	1/2*	1*	2*	2*	2*	3*
iii. Indinavir (IDV)	1/2*	1*	1/2*	1*	1	1	1	1
iv. Nelfinavir (NFV)	1/2*	1*	1/2*	1*	2*	1*	2*	2*
e. CCR5 co-receptor antagonists								
i. Maraviroc (MVC)	1/2*	1*	1/2*	1*	1	1	1	1
f. HIV integrase strand transfer inhibitors								
i. Raltegravir (RAL)	1/2*	1*	1/2*	1*	1	1	1	1
ii. Dolutegravir (DTG)	1/2*	1*	1/2*	1*	1	1	1	1
iii. Elvitegravir (EVG)	1/2*	1*	1/2*	1*	1	1	1	1
g. Fusion inhibitors								
i. Enfuvirtide	1/2*	1*	1/2*	1*	1	1	1	1
Anticonvulsant therapy								
a. Certain anticonvulsants (phenytoin, carbamazepine, barbiturates, primidone, topiramate, and oxcarbazepine)	1		1		2*	1*	3*	3*
b. Lamotrigine	1		1		1	1	1	3*
Antimicrobial therapy								
a. Broad-spectrum antibiotics	1		1		1	1	1	1
b. Antifungals	1		1		1	1	1	1
c. Antiparasitics	1		1		1	1	1	1
d. Rifampin or rifabutin therapy	1		1		2*	1*	3*	3*
Psychotropic medications								
a. SSRIs	1		1		1	1	1	1
St. John's wort	1		1		2	1	2	2

Abbreviations: BMI = body mass index; COC = combined oral contraceptive; Cu-IUD = copper-containing IUD; DMPA = depot medroxyprogesterone acetate; DVT = deep venous thrombosis; hCG = human chorionic gonadotropin; HDL = high-density lipoprotein; HIV = human immunodeficiency virus.; IUD = intrauterine device; LDL = low-density lipoprotein; LNG-IUD = levonorgestrel-releasing IUD; NA = not applicable; PE = pulmonary embolism; PID = pelvic inflammatory disease; POP = progestin-only pill; SSRI = selective serotonin reuptake inhibitor; STD = sexually transmitted disease.

#### References

 The Criteria Committee of the New York Heart Association. Nomenclature and criteria for diagnosis of diseases of the heart and great vessels. 9th ed. Boston, MA: Little, Brown & Co; 1994.

<sup>\*</sup> Consult the appendix for this contraceptive method for a clarification to this classification.

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