

South Carolina Joint Protocol for Pharmacists
Administering and Dispensing Hormonal Contraception
(issued November 16, 2022)

I. Introduction and Authorization

A pharmacist licensed under the South Carolina Pharmacy Practice Act who is acting in good faith and exercising reasonable care as a pharmacist and who is employed by a hospital or a pharmacy that is permitted by this State may dispense a self-administered hormonal contraceptive or administer an injectable hormonal contraceptive pursuant to a standing order by a prescriber consistent with this joint protocol. This joint protocol is issued by the Board of Medical Examiners and Board of Pharmacy pursuant to the Pharmacy Access Act, with approval by the Department.

II. Definitions

As used in this chapter:

- (1) 'Administer' has the same meaning as in Section 40-43-30.
- (2) 'Department' means the Department of Labor, Licensing and Regulation.
- (3) 'Dispense' has the same meaning as in Section 40-43-30.
- (4) 'Injectable hormonal contraceptive' means a drug composed of a hormone or a combination of hormones that is approved by the United States Food and Drug Administration to prevent pregnancy and that a practitioner administers to a patient by injection. 'Injectable hormonal contraceptive' does not include any drug intended to terminate a pregnancy.
- (5) 'Patient counseling' has the same meaning as in Section 40-43-30.
- (6) 'Pharmacist' has the same meaning as in Section 40-43-30.
- (7) 'Practitioner' has the same meaning as in Section 40-47-20.
- (8) 'Prescriber' means a physician licensed pursuant to Chapter 47, Title 40; an advanced practice registered nurse licensed pursuant to Chapter 33, Title 40 and prescribing in accordance with the requirements of that chapter; or a physician assistant licensed pursuant to Article 7, Chapter 47, Title 40 and prescribing in accordance with the requirements of that article.
- (9) 'Self-administered hormonal contraceptive' means a drug composed of a hormone or a combination of hormones that is approved by the United States

Food and Drug Administration to prevent pregnancy and that the patient to whom the drug is prescribed may administer to themselves. 'Self-administered hormonal contraceptive' includes an oral hormonal contraceptive, a hormonal vaginal ring, and a hormonal contraceptive patch. 'Self-administered hormonal contraceptive' does not include any drug intended to terminate a pregnancy.

III. Qualifications

(A) Prior to dispensing self-administered hormonal contraceptives or administering injectable hormonal contraceptives pursuant to South Carolina Code § 40-43-240, a pharmacist must have completed a certificate program that has been accredited by the Accreditation Council for Pharmacy Education or a similar health authority or professional body approved by the Board of Pharmacy and the Board of Medical Examiners, as specified in the joint protocol, that is program-specific to self-administered hormonal contraceptives or injectable hormonal contraceptives, that includes the application of the United States Medical Eligibility Criteria for Contraceptive Use, and that includes other Centers for Disease Control and Prevention guidance on contraception. To maintain eligibility, a pharmacist must complete at least one hour of continuing education related to hormonal contraception per year that is accredited by ACPE or CME1.

(B) An equivalent, curriculum-based training program completed on or after January 2021 in an accredited South Carolina pharmacy school satisfies the initial education requirement. At least one hour of continuing education related to hormonal contraceptives is still required.

(C) Permit holders must allow pharmacists sufficient resources, including support staff and all required supplies/equipment, to adhere to this protocol.

IV. Informed consent and self-screening tool

(A) A pharmacist who dispenses a self-administered hormonal contraceptive or administers an injectable hormonal contraceptive pursuant to this chapter shall:

(I) For each new patient requesting contraception and at least every twelve months for each returning patient, obtain a completed self-screening risk assessment questionnaire (Appendix A) that has been approved by the Board of Pharmacy and the Board of Medical Examiners through this protocol, from the patient before dispensing the self-administered hormonal contraceptive or administering the injectable hormonal contraceptive. If the results of the assessment indicate that it is unsafe to dispense a self-administered hormonal contraceptive or administer an injectable hormonal contraceptive to a patient, then the pharmacist may not dispense a self-administered hormonal contraceptive or administer an injectable hormonal contraceptive to the patient,

shall refer the patient to a practitioner, and may not continue to dispense a self-administered hormonal contraceptive or administer an injectable hormonal contraceptive to the patient for more than twenty-four months after the date of the initial prescription without evidence that the patient has consulted with a practitioner during the preceding twenty-four months; and

- (2) provide the patient with written information regarding:
 - (a) the importance of seeing the patient's practitioner annually to obtain recommended tests and screening;
 - (b) the effectiveness and availability of long-acting reversible contraceptives as an alternative to self-administered hormonal contraceptives or injectable hormonal contraceptives;
 - (c) a copy of the record of the encounter with the patient that includes the patient's completed assessment questionnaire pursuant to item(1);
 - (d) a description of the contraceptive dispensed or administered, or the basis for not dispensing or administering a contraceptive;
 - (e) the South Carolina Medicaid program and how to apply for Medicaid benefits; and

<https://www.scdhhs.gov/Getting-Started>

[https://www.scdhhs.gov/sites/default/files/Healthy%20Connections%20M edicaid%20Brochure%20Final%2011.21.19.pdf](https://www.scdhhs.gov/sites/default/files/Healthy%20Connections%20M%20edicaid%20Brochure%20Final%2011.21.19.pdf)

- (f) the effectiveness of abstinence in preventing pregnancy and contracting a sexually transmitted infection or disease. The materials shall include the following: Abstinence is the choice not to have sex. This method is one hundred percent effective in preventing pregnancy and infection as long as all sexual contact is avoided, including vaginal, oral, and anal sex.

- (g) That self-administered hormonal contraceptives do not protect against STIs.

Digital or electronic delivery of required information is acceptable.

V. Patient Counseling

If a pharmacist dispenses a self-administered hormonal contraceptive or administers an injectable hormonal contraceptive to a patient, then the pharmacist shall, at a minimum, provide patient counseling to the patient regarding:

- (1) the appropriate administration and storage of a self-administered hormonal contraceptive, if appropriate;
- (2) any potential side effects and risks of a self-administered hormonal contraceptive or injectable hormonal contraceptive;
- (3) the need for backup contraception;
- (4) when to seek emergency medical attention; and
- (5) the risk of contracting a sexually transmitted infection or disease, along with ways to reduce the risk of contraction.

VI. Procedures

- (A) The pharmacist shall ensure that the pharmacy provides appropriate space to prevent the spread of infection and ensure confidentiality. The pharmacist shall review and obtain the completed self-assessment and seated blood pressure. Refer to Standard Procedures Algorithm (Appendix B).
- (B) The pharmacist shall dispense, if clinically appropriate, a self-administered hormonal contraceptive or administer an injectable hormonal contraceptive, or refer the patient to a practitioner. The pharmacist may select any FDA-approved hormonal contraceptive that meets the criteria in this protocol and standard procedures algorithm for individuals identified as Category 1 or 2 from the current USMEC.
- (C) If the pharmacist deems the hormonal contraceptive medication inappropriate to dispense based on the self-assessment tool and as indicated by the Summary Chart of US Medical Eligibility Criteria for Contraceptive Use and the SC Algorithm for Pharmacists to Dispense Routine Hormonal Contraceptives or the SC Algorithm for Pharmacists to Dispense and Administer Depot Medroxyprogesterone Acetate, the patient should be given a copy of the encounter, either electronically or in writing, whichever is requested by the patient, with the reason why the medication could not be dispensed. Referral should be made to the patient's primary care provider, or other reproductive health care provider or local family planning clinic if the patient is not established elsewhere.

(D) The pharmacist shall also:

- a. provide the patient with a visit summary;
- b. advise the patient to consult with a practitioner;
- c. refer any patient who may be subject to abuse to the appropriate social services agency
- d. Notify the patient's designated practitioner, if any, that a self-administered hormonal contraceptive was dispensed to the patient or that an injectable hormonal contraceptive was administered to the patient.

VII. Record keeping

(A) This record must be readily accessible, maintained for 10 years and shall include the following:

- (a) The name, address, date of birth, gender and telephone number of the patient;
- (b) A copy of the patient's responses to self-screening assessment;
- (c) The name, dose, quantity and manufacturer of the hormonal contraceptive dispensed or administered;
- (d) The date of the dispensing, and if administered, the injection site;
- (e) A signed and dated informed consent form by which the patient acknowledges counseling was given;
- (f) A record of any adverse events or complications that arose following dispensing or administration;
- (g) The name, address, license number, and telephone number of the dispensing or administering pharmacist;
- (h) A copy of the notification letter sent to the patient's designated primary care practitioner.

(B) Pharmacists must keep a printed or electronic copy of the protocol available for review.

VIII. Limitations on pharmacist administered and dispensed hormonal contraceptives

Eligible patients must be:

- (1) eighteen years of age or older; or
- (2) under eighteen years of age if the person has evidence of a previous prescription from a practitioner for a self-administered hormonal contraceptive or an injectable hormonal contraceptive. Appropriate evidence includes, but is not limited to previous AVS, rx label, copy of rx, verification from previous pharmacy, etc. This can include verbal and/or electronic verification

IX. Liability

(A) A prescriber who issues a standing prescription drug order in accordance with Section 40-43-260 is not liable for any civil damages for acts or omissions resulting from the dispensing of a self-administered hormonal contraceptive or the administering of an injectable hormonal contraceptive under this chapter.

(B) A pharmacist who dispenses a self-administered hormonal contraceptive or administers an injectable hormonal contraceptive in accordance with the provisions of this article is not as a result of an act or omission subject to civil or criminal liability or to professional disciplinary action.

X. Miscellaneous

Nothing in this section requires a pharmacist to dispense a self-administered hormonal contraceptive or administer an injectable hormonal contraceptive. Nothing in this article shall be construed to amend a pharmacist's duties to dispense or otherwise provide contraception prescribed by another provider.

South Carolina Hormonal Contraceptive Self-Screening Questionnaire

Date ___/___/___ Patient Name _____ Primary Care Provider _____

Date of Birth ___/___/___ Age _____ Weight _____ Do you have health insurance? Yes / No

What was the date of your last women's health clinical visit? _____

Any allergies to Medications? Yes / No If yes, list them here _____

Do you have a preferred method of birth control that you would like touse?

A daily pill A weekly patch A vaginal ring Injectable (every 3 months)

1	Do you think you might be pregnant now?	Yes <input type="checkbox"/> No <input type="checkbox"/>
2	What was the first day of your last menstrual period?	/___/
3	Have you ever taken birth control pills, or used a birth control patch, ring, or injection? Have you previously had contraceptives dispensed to you by a pharmacist?	Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/>
	Did you ever experience a bad reaction to using hormonal birth control?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	- If yes, what kind of reaction occurred?	_____
	Are you currently using any method of birth control including pills, or a birth control patch, ring or shot/injection?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	- If yes, which one do you use?	_____
4	Have you ever been told by a medical professional not to take hormones?	Yes <input type="checkbox"/> No <input type="checkbox"/>
5	Do you smoke cigarettes?	Yes <input type="checkbox"/> No <input type="checkbox"/>
6	Have you had a recent change in vaginal bleeding that worries you?	Yes <input type="checkbox"/> No <input type="checkbox"/>
7	Have you given birth within the past 21 days? If yes, how long ago?	Yes <input type="checkbox"/> No <input type="checkbox"/>
8	Are you currently breastfeeding?	Yes <input type="checkbox"/> No <input type="checkbox"/>
9	Do you have diabetes?	Yes <input type="checkbox"/> No <input type="checkbox"/>
10	Do you get migraine headaches?	Yes <input type="checkbox"/> No <input type="checkbox"/>
10a	If so, have you ever had the kind of headaches that start with warning signs or symptoms, such as flashes of light, blind spots, or tingling in your hand or face that comes and goes completely away before the headache starts?	Yes <input type="checkbox"/> No <input type="checkbox"/>
11	Are you being treated for inflammatory bowel disease?	Yes <input type="checkbox"/> No <input type="checkbox"/>
12	Do you have high blood pressure, hypertension, or high cholesterol? (Please indicate yes, even if it is controlled by medication)	Yes <input type="checkbox"/> No <input type="checkbox"/>
13	Have you ever had a heart attack or stroke, or been told you had any heart disease?	Yes <input type="checkbox"/> No <input type="checkbox"/>
14	Have you ever had a blood clot?	Yes <input type="checkbox"/> No <input type="checkbox"/>
15	Have you ever been told by a medical professional you are at risk of developing a blood clot?	Yes <input type="checkbox"/> No <input type="checkbox"/>
16	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	Yes <input type="checkbox"/> No <input type="checkbox"/>
17	Will you be immobile for a long period? (e.g. flying on a long airplane trip, etc.)	Yes <input type="checkbox"/> No <input type="checkbox"/>
18	Have you had bariatric surgery or stomach reduction surgery?	Yes <input type="checkbox"/> No <input type="checkbox"/>
19	Do you have or have you ever had breast cancer?	Yes <input type="checkbox"/> No <input type="checkbox"/>
20	Have you had a solid organ transplant?	Yes <input type="checkbox"/> No <input type="checkbox"/>
21	Do you have or have you ever had hepatitis, liver disease, liver cancer, or gall bladder disease, or do you have jaundice (yellow skin or eyes)?	Yes <input type="checkbox"/> No <input type="checkbox"/>
22	Do you have lupus, rheumatoid arthritis, or any blood disorders?	Yes <input type="checkbox"/> No <input type="checkbox"/>
23	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?	Yes <input type="checkbox"/> No <input type="checkbox"/>
	- If yes, list them here:	
24	Do you have any other medical problems or take any medications, including herbs or supplements? If yes, list them here:	Yes <input type="checkbox"/> No <input type="checkbox"/>

Signature _____

Date _____

Appendix B

Date ____/____/____

BP Reading ____/____ *Must be taken by RPH

Note: RPH must refer patient if either systolic or diastolic reading is out of range, per algorithm

Rx

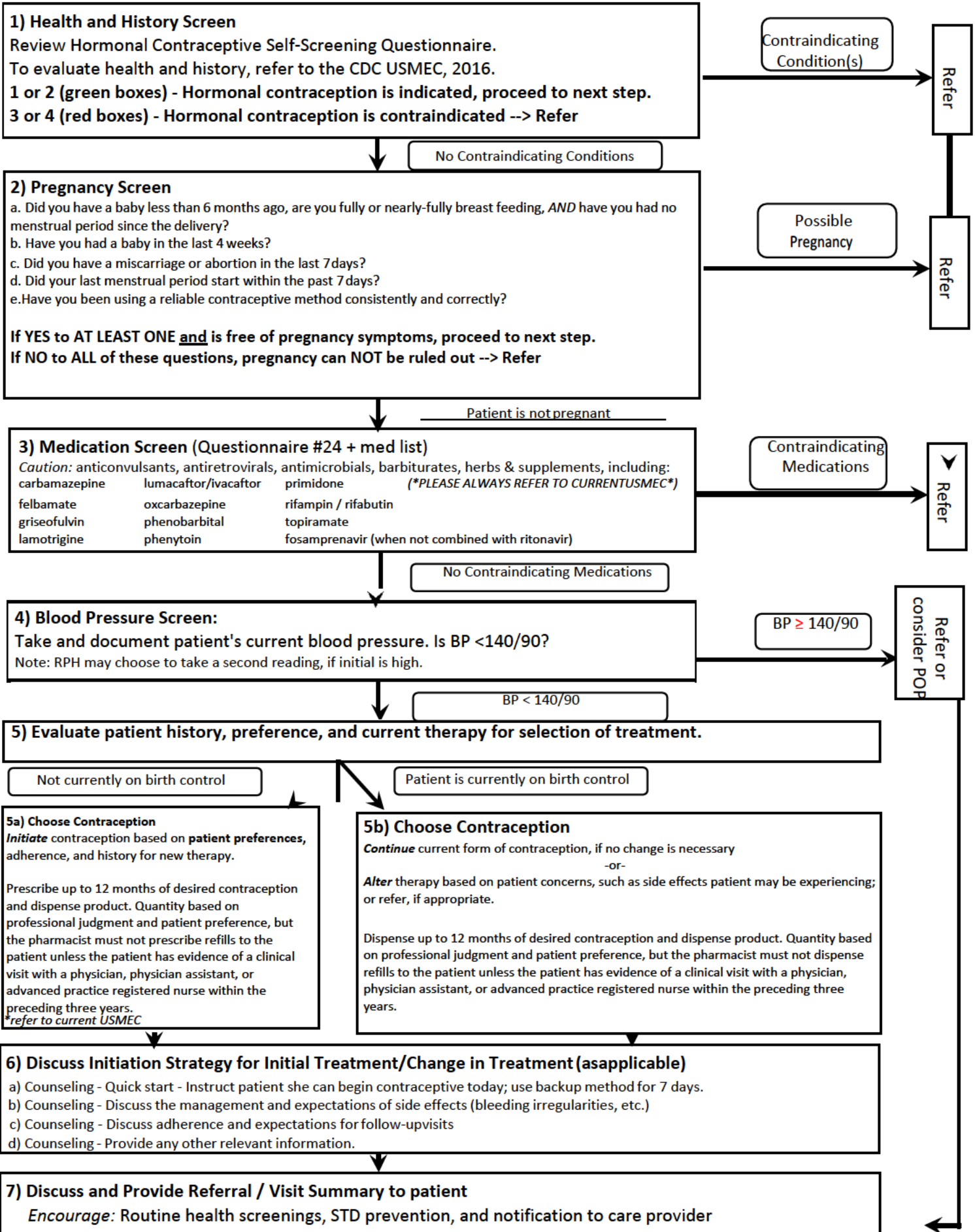
Drug Dispensed _____ Rx _____

Directions for Use _____

Pharmacist Name _____ RPH Signature _____

Pharmacy Address _____ Pharmacy Phone _____

SOUTH CAROLINA BOARD OF PHARMACY STANDARD PROCEDURES ALGORITHM FOR PRESCRIBING OF CONTRACEPTIVES*



Summary Chart of U.S. Medical Eligibility Criteria for Contraceptive Use

Updated July 2017.* This summary sheet only contains a subset of the recommendations from the USMEC. It is color coded in the left column to match the corresponding question of the Vermont Board of Pharmacy Self-Screening Risk Assessment Questionnaire.

Key:	
1	No restriction (method can be used)
2	Advantages generally outweigh theoretical or proven risks
3	Theoretical or proven risks usually outweigh the advantages
4	Unacceptable health risk (method not to be used)

For complete guidance, see: <http://www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm>

Note: Most contraceptive methods do not protect against sexually transmitted diseases (STDs). Consistent and correct use of the male latex condom reduces the risk of STDs and HIV.

Corresponding to the South Carolina Self-Screening Risk Assessment Questionnaire:

Condition	Sub-condition	Combined pill, patch (CHC)		Progestin-only Pill (POP)		DMPA (Inj)		Other Contraception Options Indicated for Patient
		Initiating	Continuing	Initiating	Continuing	Initiating	Continuing	
a. Age	Menarche to <40	1	1	1	1	1	1	Yes
	>40	2	2	2	2	2	2	Yes
b. Smoking	a) Age < 35	2	2	1	1	1	1	Yes
	b) Age > 35, < 15 cigarettes/day	3	3	1	1	1	1	Yes
c. Pregnancy	c) Age > 35, >15 cigarettes/day (Not Eligible for contraception)	4	4	1	1	1	1	Yes
		NA*	NA*	NA*	NA*	NA*	NA*	NA*
d. Vaginal Bleeding	Unexplained or worrisome vaginal bleeding	2	2	2	2	3	3	Yes
	a) < 21 days	4	4	1	1	1	1	Yes
e. Postpartum (see also Breastfeeding)	b) 21 days to 42 days:							
	(i) with other risk factors for VTE	3*	3*	1	1	1	1	Yes
	(ii) without other risk factors for VTE	2	2	1	1	1	1	Yes
	c) > 42 days	1	1	1	1	1	1	Yes
f. Breastfeeding (see also Postpartum)	a) < 1 month postpartum	3/4*	3/4*	2*	2*	2*	2*	Yes
	b) 30 days to 42 days:							
	(i) with other risk factors for VTE	3*	3*	2*	2*	2*	2*	Yes
	(ii) without other risk factors for VTE	2*	2*	1*	1*	1*	1*	Yes
g. Diabetes mellitus (DM)	c) > 42 days postpartum	2*	2*	1*	1*	1*	1*	Yes
	a) History of gestational DM only	1	1	1	1	1	1	Yes
	b) Non-vascular disease							
	(i) non-insulin dependent	2	2	2	2	2	2	Yes
	(ii) insulin dependent†	2	2	2	2	2	2	Yes
h. Headaches	c) Nephropathy/ retinopathy/ neuropathy‡	3/4*	3/4*	2	2	3	3	Yes
	d) Other vascular disease or diabetes of >20 years' duration‡	3/4*	3/4*	2	2	3	3	Yes
	a) Non-migrainous	1*	1*	1	1	1	1	Yes
i. Inflammatory Bowel Disease	b) Migraine:							
	(i) without aura (includes menstrual migraines)	2*	2*	1	1	1	1	Yes
	(ii) with aura	4*	4*	1	1	1	1	Yes
j. Hypertension	a) Mild; no risk factors	2	2	2	2	2	2	Yes
	b) IBD with increased risk for VTE	3	3	2	2	2	2	Yes
	a) Adequately controlled hypertension	3*	3*	1*	1*	2*	2*	Yes
k. History of high blood pressure during pregnancy	b) Elevated blood pressure levels (properly taken measurements):							
	(i) systolic 140-159 or diastolic 90-99	3*	3*	1*	1*	2*	2*	Yes
	(ii) systolic ≥160 or diastolic ≥100‡	4*	4*	2*	2*	3*	3*	Yes
l. Peripartum cardiomyopathy‡	c) Vascular disease	4*	4*	2*	2*	3*	3*	Yes
	a) Normal or mildly impaired cardiac function:							
	(i) < 6 months	4	4	1	1	1	1	Yes
m. Multiple risk factors for arterial CVD	(ii) > 6 months	3	3	1	1	1	1	Yes
	b) Moderately or severely impaired cardiac function	4	4	2	2	2	2	Yes
n. Ischemic heart disease‡	(such as older age, smoking, diabetes, hypertension, low HDL, high LDL, or high triglyceride levels)	3/4*	3/4*	2*	2*	3*	3*	Yes
	Current and history of	4	4	2	2	3	3	Yes
o. Valvular heart disease	a) Uncomplicated	2	2	1	1	1	1	Yes
	b) Complicated‡	4	4	1	1	1	1	Yes
p. Stroke‡	History of cerebrovascular accident	4	4	2	2	3	3	Yes
	q. Known Thrombogenic mutations‡	4*	4*	2*	2*	2*	2*	Yes

*Adapted, with kind permission, from document prepared by the Vermont Board of Pharmacy

I = initiation of contraceptive method; C = continuation of contraceptive method; NA = Not applicable

† Please see the complete guidance for a clarification to this classification: www.cdc.gov/reproductivehealth/unintendedpregnancy/USMEC.htm

‡ Condition that exposes a woman to increased risk as a result of unintended pregnancy.