Vermont Pharmacist Prescribing Protocol – Self-Administered Hormonal Contraceptives

Background

A pharmacist may prescribe, order, or administer self-administered hormonal contraceptives in a manner consistent with a valid State protocol approved by the Commissioner of Health, after consultation with the Director of Professional Regulation and the Board of Pharmacy (BOP). 26 V.S.A. § 2023(b)(2)(A)(i).

Pharmacists who independently prescribe self-administered hormonal contraceptives must follow this protocol. When prescribing per this protocol, the pharmacist is the prescriber-of-record.

Definitions

Per 26 V.S.A. § 2022 (21) "Self-administered hormonal contraceptives" means a contraceptive medication or device approved by the U.S. Food and Drug Administration that prevents pregnancy by using hormones to regulate or prevent ovulation and that uses an oral, transdermal, or vaginal route of administration.

"Recipient" means a person capable of becoming pregnant and who wished to use hormonal contraception

General considerations

Prescribing self-administered hormonal contraceptives under this protocol requires the pharmacist to:

1. Have training and education in that area sufficient to perform the duties involved
2. Document prescribing, including notifying the patient's primary care provider within 5 business days.
3. Keep a written copy of the protocol at each location from where prescriptions are issued for a self-administered hormonal contraceptive
4. Provide a copy of the protocol available upon the request of an inspector.

Procedures

When an individual requests a prescription for self-administered hormonal contraceptives, or when a pharmacist in his or her professional judgement offers to prescribe self-administered hormonal contraceptives to an individual, the pharmacist shall:

1. Direct the patient to the counseling area, as required in Administrative Rule 9.2, to provide reasonable privacy
2. Prescribe a contraceptive only if the intended use is contraception
3. Have the patient complete the *Vermont Hormonal Contraceptive Self-Screening Questionnaire*, in the primary language spoken by the patient
    a. A prescription cannot be issued if a patient does not compete the questionnaire
    b. A patient must complete the questionnaire at least once every 12 months
    c. Questionnaires should be kept on file for a minimum of 2 years
4. Review of the completed questionnaire with the patient and clarify responses, if necessary.
5. Measure and record the patient's, seated, blood pressure
6. The *Vermont Board of Pharmacy Standard Procedures Algorithm for Prescribing of Contraceptives*, on page 4, is available as a guide for this process. Evaluation of the patient's health and history should be in accordance with the most current United States Medical Eligibility Criteria (US MEC) for Contraceptive Use, as adopted by the US Centers of Disease Control and Prevention (CDC). The summary chart of the US MEC for Contraceptive Use, from the CDC's website may be used, or, the Summary Chart of the US MEC for Contraceptive Use in this protocol that has been color-coded to correspond to the *Vermont Hormonal Contraceptive Self-Screening Questionnaire*

a. Only if the evaluation indicates no contraindications to hormonal contraceptives exist, may a prescription be issued to the patient
b. If the evaluation indicates the patient should be referred to their primary care provider (PCP), or clinic/hospital if the patient doesn't have a PCP, the pharmacist shall not issue a prescription, and shall make the referral and provide a written visit summary (the *Pharmacist Referral and Visit Summary* template below may be used for this purpose).

7. When a prescription for a hormonal contraceptive is issued, counsel the patient in accordance with Vermont's Administrative Rules and provide written patient education materials about the drug prescribed. Counseling should include providing any necessary training for self-administration of the hormonal contraceptive prescribed, if needed.
8. When a prescription for a hormonal contraceptive is issued, provide to the patient a written record of the medication prescribed (the *Pharmacist Referral and Visit Summary* template below may be used for this purpose).
9. Determine if the patient has a primary care clinician and encourage them to seek routine primary care. If the patient does not have a primary care clinician, provide referral to patient for finding primary care services, such as VT-211 or, for Medicaid beneficiaries, the Vermont Medicaid Provider lookup .

Authorized Drugs

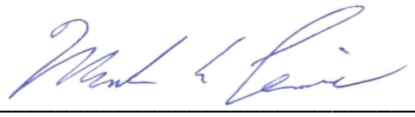
Prescribing and dispensing done pursuant to this protocol is limited to FDA-approved, self-administered hormonal contraceptives, as defined in 26 V.S.A. § 2022 (21).

Prescribing Records

The pharmacist must generate a written or electronic prescription for any self-administered hormonal contraceptive pursuant to protocol-base prescribing. The prescription must include all the information required by Administrative Rule 10.1. The prescription must be processed in the same manner that any other prescription is processed, pursuant to the applicable statutes and rules for the dispensing of prescription drugs. The prescription shall be kept on file and maintained for a minimum of three years, as required by the rules of the Vermont BOP. Pharmacists are reminded to adhere to record-keeping requirements for prescriptions paid for by Medicare and Medicaid, which may differ from those required by BOP.

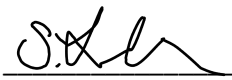
Vermont Pharmacist Prescribing Protocol – Self-Administered Hormonal Contraceptives

APPROVED:



Commissioner, Vermont Department of Health

Date: 6/21/21



Director, Office of Professional Regulation

Date: 6/21/2021

Pharmacist Referral and Visit Summary

Patient Name:_____ Date of birth:_____ Date: _____

Self-administered hormonal contraceptive prescribed today: _____
Quantity prescribed: _____ Refills authorized: _____

If you have a question, my name is _____

Please review the information above with your primary care or women's health provider.

OR

____I am not able to prescribe hormonal contraception to you today, because:

□ Pregnancy cannot be ruled out. *(Notes:_____)*

□ You have a health condition than requires further evaluation. *(Notes:_____)*

□ You take medication(s) or supplements that may interfere with contraceptives. *(Notes:_____)*

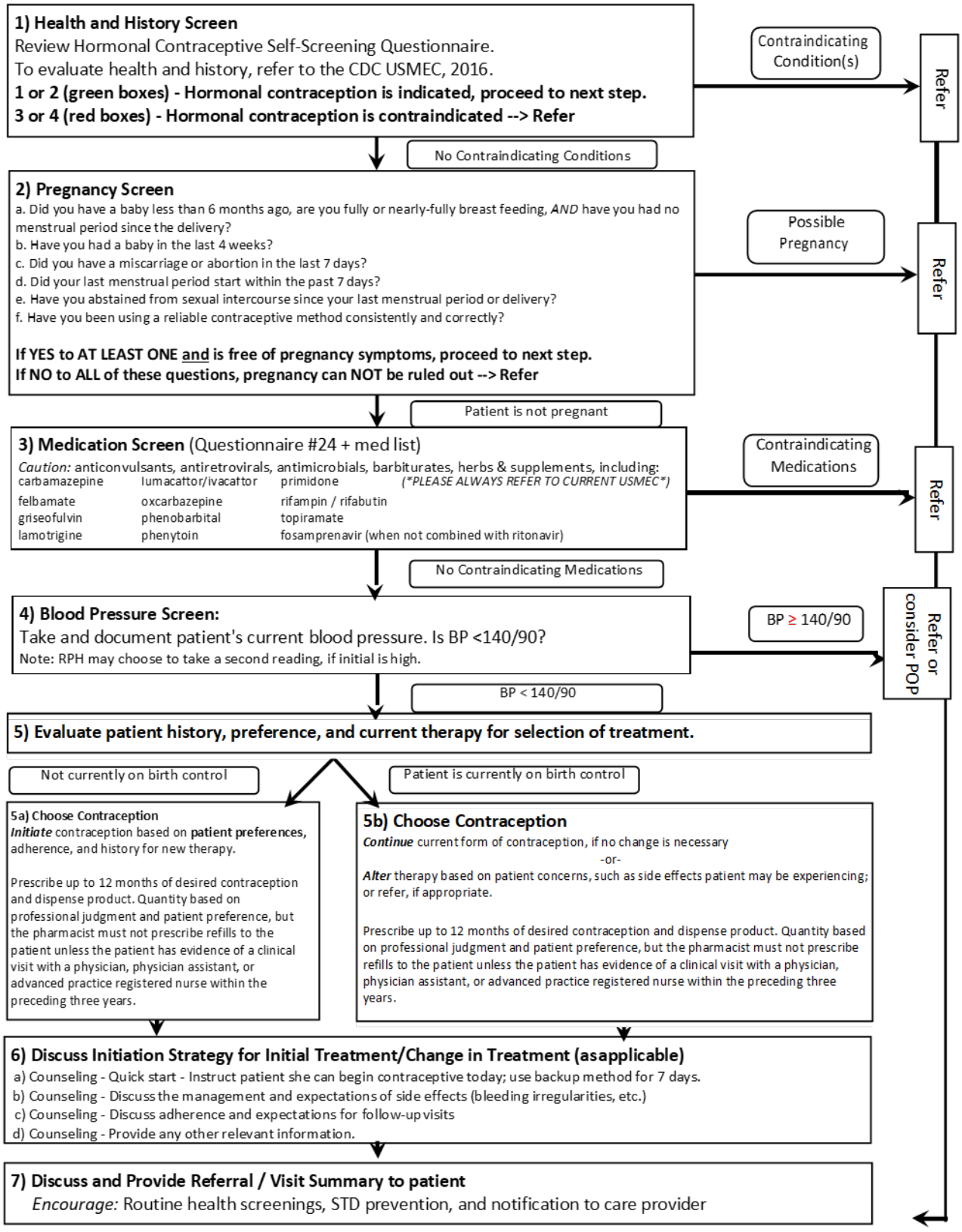
□ Your blood pressure reading is higher than 140/90. *(_____/_____)*

Each requires additional evaluation by another healthcare provider. Please share this information with your provider.

Pharmacist Name _____
Pharmacy Name _____
Pharmacy Address _____
Pharmacy Phone Number _____

***Attention Pharmacy**: This is a template document. Please feel free to customize it to your particular company, however you **must retain all elements** set forth by this template.*

VERMONT BOARD OF PHARMACY STANDARD PROCEDURES ALGORITHM FOR PRESCRIBING OF CONTRACEPTIVES*



Adapted from Minnesota Board of Pharmacy Algorithm

Vermont Hormonal Contraceptive Self-Screening Questionnaire

Patient Name_____Health Care Provider's Name_____ Date_____
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 to use?

□ a daily pill □ a weekly patch □ a vaginal ring

Background Information:

1	Do you think you might be pregnant now?	Yes □ No□
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?	Yes □ No □
	Have you previously had contraceptives prescribed to you by a pharmacist?	Yes □ No □
	Did you ever experience a bad reaction to using hormonal birth control?	Yes □ No □
	- 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 □ No □
	- If yes, which one do you use?	_____
4	Have you ever been told by a medical professional not to take hormones?	Yes □ No □
5	Do you smoke cigarettes?	Yes □ No □

Medical History:

6	Have you had a recent change in vaginal bleeding that worries you?	Yes □ No □
7	Have you given birth within the past 21 days? If yes, how long ago?	Yes □ No □
8	Are you currently breastfeeding?	Yes □ No □
9	Do you have diabetes?	Yes □ No □
10	Do you get migraine headaches?	Yes □ No □
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 □ No □
11	Are you being treated for inflammatory bowel disease?	Yes □ No □
12	Do you have high blood pressure, hypertension, or high cholesterol? (Please indicate yes, even if it is controlled by medication)	Yes □ No □
13	Have you ever had a heart attack or stroke, or been told you had any heart disease?	Yes □ No □
14	Have you ever had a blood clot?	Yes □ No □
15	Have you ever been told by a medical professional you are at risk of developing a blood clot?	Yes □ No □
16	Have you had recent major surgery or are you planning to have surgery in the next 4 weeks?	Yes □ No □
17	Will you be immobile for a long period? (e.g. flying on a long airplane trip, etc.)	Yes □ No □
18	Have you had bariatric surgery or stomach reduction surgery?	Yes □ No □
19	Do you have or have you ever had breast cancer?	Yes □ No □
20	Have you had a solid organ transplant?	Yes □ No □
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 □ No □
22	Do you have lupus, rheumatoid arthritis, or any blood disorders?	Yes □ No □
23	Do you take medication for seizures, tuberculosis (TB), fungal infections, or human immunodeficiency virus (HIV)?	Yes □ No □
	- If yes, list them here:	
24	Do you have any other medical problems or take any medications, including herbs or supplements?	Yes □ No □
	- If yes, list them here:	

*Signature*_____*Date*_____

Adapted, with kind permission, from Minnesota Board of Pharmacy Self-Screening Questionnaire

Vermont Hormonal Contraceptive Self-Screening Questionnaire: Optional Side *– May be used by the prescribing pharmacist. This side of form may be customized by prescribing pharmacist – Do not make edits to the Questionnaire (front side)*

Pregnancy Screen	
a. Did you have a baby less than 6 months ago, are you fully or nearly-fully breast feeding, AND have you had no menstrual period since the delivery?	Yes □ No □
b. Have you had a baby in the last 4 weeks?	Yes □ No □
c. Did you have a miscarriage or abortion in the last 7 days?	Yes □ No □
d. Did your last menstrual period start within the past 7 days?	Yes □ No □
e. Have you abstained from sexual intercourse since your last menstrual period or delivery?	Yes □ No □
f. Have you been using a reliable contraceptive method consistently and correctly?	Yes □ No □

☐ verified DOB with valid photo ID ☐ BP Reading_____/_____**Must be taken by RPH*

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

℞

Drug Prescribed_____Rx_____
Directions for Use _____
Pharmacist Name_____RPH Signature _____
Pharmacy Address_____Pharmacy Phone _____

☐

_____
_____
_____

Adapted, with kind permission, from Minnesota Board of Pharmacy Self-Screening Questionnaire

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.

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

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)

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 Vermont* 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		Menarche to <18=1		Menarche to <18=2		Yes
		>40=2		18-45=1		18-45=1		Yes
				>45=1		>45=2		Yes
b. Smoking	a) Age < 35	2		1		1		Yes
	b) Age > 35, < 15 cigarettes/day	3		1		1		Yes
	c) Age > 35, >15 cigarettes/day	4		1		1		Yes
c. Pregnancy	(Not Eligible for contraception)	NA*		NA*		NA		NA*
d. Vaginal Bleeding	Unexplained or worrisome vaginal bleeding	2		2		3		Yes
e. Postpartum (see also Breastfeeding)	a) < 21 days	4		1		1		Yes
	b) 21 days to 42 days:							
	(i) with other risk factors for VTE	3*		1		1		Yes
	(ii) without other risk factors for VTE	2		1		1		Yes
	c) > 42 days	1		1		1		Yes
f. Breastfeeding (see also Postpartum)	a) < 1 month postpartum	3/4*		2*		2*		Yes
	b) 30 days to 42 days							
	(i) with other risk factors for VTE	3*		2*		2*		Yes
	(ii) without other risk factors for VTE	2*		1*		1*		Yes
	c)> 42 days postpartum	2*		1*		1*		Yes
g. Diabetes mellitus (DM)	a) History of gestational DM only	1		1		1		Yes
	b) Non-vascular disease							
	(i) non-insulin dependent	2		2		2		Yes
	(ii) insulin dependent‡	2		2		2		Yes
	c) Nephropathy/ retinopathy/ neuropathy‡	3/4*		2		3		Yes
	d) Other vascular disease or diabetes of >20 years' duration‡	3/4*		2		3		Yes
h. Headaches	a) Non-migrainous	1*		1		1		Yes
	b) Migraine:							
	i) without aura (includes menstrual migraines)	2*		1		1		Yes
	iii) with aura	4*		1		1		Yes
i. Inflammatory Bowel Disease	a) Mild; no risk factors	2		2		2		
	b) IBD with increased risk for VTE	3						
j. Hypertension	a) Adequately controlled hypertension	3*		1*		2*		Yes
	b) Elevated blood pressure levels (properly taken measurements):							
	(i) systolic 140-159 or diastolic 90-99	3*		1*		2*		Yes
	(ii) systolic ≥160 or diastolic ≥100‡	4*		2*		3*		Yes
	c) Vascular disease	4*		2*		3*		Yes
k. History of high blood pressure during pregnancy		2		1		1		Yes
l. Peripartum cardiomyopathy‡	a) Normal or mildly impaired cardiac function:							
	(i) < 6 months	4		1		1		Yes
	(ii) > 6 months	3		1		1		Yes
	b) Moderately or severely impaired cardiac function	4		2		2		Yes
m. Multiple risk factors for arterial CVD	(such as older age, smoking, diabetes, hypertension, low HDL, high LDL, or high triglyceride levels)	3/4*		2*		3*		Yes
n. Ischemic heart disease‡	Current and history of	4		2	3	3		Yes
o. Valvular heart disease	a) Uncomplicated	2		1		1		Yes
	b) Complicated‡	4		1		1		Yes
p. Stroke‡	History of cerebrovascular accident	4		2	3	3		Yes
q. Known Thrombogenic mutations‡		4*		2*		2*		Yes

**Adapted, with kind permission, from document prepared by the Minnesota 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.