Pharmacy Name: _____

Pharmacy Permit Number: _____

SELF-CARE CONDITIONS: HORMONAL CONTRACEPTION PROTOCOL
V1
Approved 09/25/2024

PURPOSE
This protocol specifies the criteria and procedures for pharmacist(s) to initiate the dispensing of self-care hormonal contraceptives.

PHARMACIST EDUCATION AND TRAINING
Prior to initiating the dispensing of hormonal contraception therapy under this protocol, pharmacist(s) must have received education and training on hormonal contraception provision from a provider accredited by the Accreditation Council for Pharmacy Education, or by a comparable provider approved by the Kentucky Board of Pharmacy.

CRITERIA
Pharmacist(s) authorized to initiate the dispensing of hormonal contraception therapy will follow the most current US Medical Eligibility Criteria (US MEC) for Contraceptive Use put forth by the Centers for Disease Control and Prevention (CDC), limiting provision to therapies listed as either category 1 or 2 for any applicable condition/sub-condition.[1]

Inclusion criteria:
- Any individual seeking maintenance hormonal contraception for the purpose of preventing pregnancy

Exclusion criteria:
- Individuals with male sex assigned at birth
- Individuals with conditions listed as category 3 or 4 in the US MEC for progestin-only pills (POPs)
- Hypersensitivity to norgestrel or any ingredients contained in the dispensed drug product
- Concurrent use of another birth control pill, vaginal ring, patch, implant, injection, or intrauterine device (IUD)
- Use of ulipristal acetate within the previous 5 days
- Pregnant individuals or those presenting with symptoms consistent with pregnancy and reporting unprotected/inadequately protected intercourse following their last menstrual period

[1] *US Medical Eligibility Criteria (US MEC) for Contraceptive Use, 2024 | CDC. Published August 6, 2024. Accessed August 15, 2024.* https://www.cdc.gov/contraception/hcp/usmec/index.html

MEDICATIONS

This protocol authorizes pharmacist(s) to initiate the dispensing of the following medication regimen to an individual meeting criteria:

- **Norgestrel 0.075mg once daily at the same time each day**

PROCEDURES FOR INITIATION OF THERAPY

Hormonal contraception initiation will follow current guidelines[1] and will be individualized based on relevant medical, sexual, and social history, patient preferences, and consideration of contraindications and precautions of therapy as outlined below. Refer patient as needed if the patient wishes to seek alternatives not included within this protocol.

Relevant Medical and Social History

- Past medical history
- Sexual history
- Current medications
- Allergies and hypersensitivities

Precautions

- Conditions/circumstances that may limit the effectiveness of the hormonal contraception regimen, including:
  - Concurrent medications (e.g., CYP3A4 Inducers) that may decrease the effectiveness of norgestrel
- Norgestrel should be taken at the same time each day to ensure effectiveness

DURATION OF THERAPY

This protocol authorizes pharmacist(s) to initiate the dispensing of up to a 1-year supply of a medication listed above to individuals who meet criteria

EDUCATION REQUIREMENTS

Individuals receiving hormonal contraception therapy under the protocol will receive education regarding:

- Education regarding safe sexual practices, including the necessity of protection for sexually transmitted infections.
- Refer as needed for provision of permanent or long-acting reversible contraception (LARC), sexually transmitted infection testing, gynecological examinations, other desired contraceptive forms, emergency contraception, and well-woman care.
- Education specific to the norgestrel, including conditions or medications that may decrease the effectiveness or increase risk of norgestrel. This will include (but is not limited to):

    - Use of barrier contraceptive methods for 48 hours after starting/restarting norgestrel upon initiation and if a dose of norgestrel is missed or taken >3 hours later than usual.
    - Norgestrel is NOT an emergency contraceptive
    - Individuals who miss two periods (or a single period and have missed doses of norgestrel) or suspect they may be pregnancy should take a pregnancy test and, if confirmed, discontinue norgestrel.
    - Cannot be taken within 5 days following use of ulipristal acetate. If initiated after 5 days, barrier contraceptive methods should be used until the next menstral period.
- Education regarding the necessity of a visit to a primary care provider or urgent/emergency treatment facility if any of the following occur:
    - Unscheduled or breakthrough bleeding that persists for more than a few cycles
    - Signs of an allergic reaction, such as rash, itching, tightness in chest or throat, trouble breathing or swallowing, or swelling of the face, lips, mouth, tongue, or throat.

DOCUMENTATION

Pharmacist(s) shall document via prescription record each person who receives hormonal contraception therapy under this protocol, including:

- Documentation as required in 201 KAR 2:171 for the dispensing of prescription medication; and
- Documentation that the individual receiving the hormonal contraception (or caregiver) was provided with the required education pursuant to this protocol
- Documentation of the history and assessment, the plan of care implemented, and follow-up monitoring and evaluation.

NOTIFICATION

Pharmacist(s) shall ask all persons receiving hormonal contraception therapy under this protocol for the name and contact information of the individual's primary care provider and shall provide notification of the medications dispensed under the protocol to the identified primary care provider within two (2) business days. Any individual affirmatively stating that the individual does not have a primary care provider may still be provided hormonal contraception therapy under this protocol provided all other applicable requirements of the protocol are met.

[If directed by the authorizing prescriber, the pharmacist(s) shall provide written notification via fax or other secure electronic means to the authorizing prescriber of persons receiving medications under this protocol within 7 days of initiating dispensing.]

TERMS

This protocol is authorized pursuant to 201 KAR 2:380 and is effective when it is submitted to the registry. Any termination shall require prior notice to all parties no later than 30 days after discontinuing the protocol.

SIGNATURES

_____ _____

Prescriber Name Date

_____

Prescriber Kentucky License Number

_____

Prescriber Signature

_____ _____

Pharmacist Name Date

_____

Pharmacist Kentucky License Number

_____

Pharmacist Signature

Course Taken for Training: _____

Provider of Training: _____

Date Training Completed: _____

Any pharmacist not party to the protocol will be subject to discipline should they utilize the protocol. A pharmacist utilizing the protocol must be employed by or contracted with the permit listed in the executed protocol.

For additional pharmacists party to this protocol, the pharmacy should keep a list of the additional pharmacists and their training at the pharmacy.

ADDITIONAL SIGNATURE PAGE

By signing below, I attest that I read and understand the Board-authorized protocol, entitled : _____
and that I will follow all guidelines and requirements included in the Board-authorized protocol.

_____ _____
Pharmacist Name Date

_____
Pharmacist Kentucky License Number

_____
Pharmacist Signature

Course Taken for Training: _____

Provider of Training: _____

Date Training Completed: _____