Pharmacy Name: _____

Pharmacy Permit Number: _____

SELF-CARE CONDITIONS: OVER-THE-COUNTER PROBIOTICS PROTOCOL
Approved
07/24/2024
V2

PURPOSE

This protocol specifies the criteria and procedures for pharmacist(s) to initiate the dispensing of over-the- counter probiotic therapies.

PHARMACIST EDUCATION AND TRAINING

Prior to initiating the dispensing of probiotic therapy under this protocol, pharmacist(s) must have received education and training in probiotic therapies 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 probiotic therapy will follow the current World Gastroenterology Organisation Global Guidelines on Probiotics and Prebiotics.[1]

Inclusion criteria:

- Patients that may benefit from probiotic therapy or adjunct probiotic therapy with history of or for prevention of the following conditions:
    - Acute gastroenteritis
    - Antibiotic associated diarrhea or yeast infections
    - Clostridium difficile associated diarrhea
    - Eczema
    - Irritable bowel syndrome
    - Irregular bowel movements
    - Any other clinical application listed in the current World Gastroenterology Organizational Global Guidelines on Probiotics and Prebiotics.[1]

Exclusion criteria:

- Any individual who has an allergy or contraindication to therapy due to drug-drug interactions
- Any individual who has an immunocompromised disease state or who

is currently on immunocompromising therapies.

MEDICATIONS

This protocol authorizes pharmacists to initiate the dispensing of over-the-counter probiotic therapy using the doses consistent with the product labeling that meet the following criteria:

- Have been manufactured in an FDA registered facility
- Probiotic product/strain has approval or GRAS (generally recognized as safe) status with the Food and Drug Administration (FDA)[2],
- Contains no additional active ingredients that would require prescriptive permission, and
- Contains products/strains for the appropriate indication as identified by the current World Gastroenterology Organisation Global Guidelines on Probiotics and Prebiotics[1].

PROCEDURES FOR INITIATING THERAPY

Probiotic therapy initiation and monitoring will be individualized based on relevant medical and social history, patient preferences, and consideration of contraindications and precautions of therapy as outlined below.

- Relevant Medical and Social History
  - Past medical history
  - Current medications
  - Allergies and hypersensitivities
- Contraindications and Precautions
  - Known hypersensitivities to probiotic product ingredients (as listed on the product label)
  - Potential drug-drug interactions based on current medications

PROCEDURES FOR MONITORING AND CONTINUATION OF THERAPY

Follow-up monitoring and evaluation to determine effectiveness, adverse effects, and patient progress with therapy is required if therapy is to continue following the initial dispensation. If follow-up monitoring and evaluation indicates therapy continuation is warranted, medication refills may be authorized.

If signs of an allergic reaction occur, such as hives, itching, rash, red and swollen skin, difficulty breathing, medication will be discontinued, and the patient referred to an emergency care or primary care provider.

Should follow-up evaluation and monitoring indicate an adjustment in therapy is warranted, all procedures as outlined for initiation of therapies, including education, documentation, and notification, will be followed.

PATIENT EDUCATION REQUIREMENTS

Patient(s) receiving probiotic therapies under the protocol will receive education regarding:

- Storage requirements
- Directions for use
- Duration of therapy
- Potential adverse effects
- Action if dose is missed

DOCUMENTATION

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

- Documentation as required in 201 KAR 2:171 for the dispensing of prescription medications
- Documentation that the individual receiving the probiotics was provided with the required education pursuant to this protocol, and
- Documentation of the clinical indication for probiotic therapy, probiotic product/strain dispensed, plan of care implemented, and follow-up monitoring and evaluation

NOTIFICATION

Pharmacist(s) shall ask all persons receiving probiotics under this protocol for the name and contact information of the individual's primary care provider and shall provide notification of the probiotics 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 receive probiotics 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 probiotic therapies under this protocol within 7 days of initiating dispensing]

Resources Available Online for Pharmacist Reference and Used in the Development of this Protocol:

[1]Francisco G, Mary Ellen S, Rami E, et al. World Gastroenterology Organization Global Guidelines: Probiotics and prebiotics. https://www.worldgastroenterology.org/guidelines/probiotics-and-prebiotics/probiotics-and-prebiotics-english. Published February 2023. Accessed April 2024.

[2]Generally recognized as safe (GRAS). U.S. Food and Drug Administration website https://www.fda.gov/food/generally-recognized-safe-gras/gras-substances-scogs-database . Accessed April 2024.

[3]Dragana S, Vivien B, Bradley J, et al. Clinical Guide to Probiotic Products; Indications, dosage forms and clinical evidence to date. BHSoftInc. Updated 2024; valid until December 31 2024. Available at: www.usprobioticguide.com.

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: _____