Pharmacy Name: _____

Pharmacy Permit Number: _____

SELF-CARE CONDITIONS: OVER-THE COUNTER DIETARY SUPPLEMENT 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 dietary supplement therapy.

PHARMACIST EDUCATION AND TRAINING

Prior to initiating the dispensing of over-the-counter dietary supplements under this protocol, pharmacist(s) must have received education and training in dietary supplement therapy 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 over-the-counter dietary supplement therapy will follow the current World Gastroenterology Organizational Global Guidelines on Probiotics and Prebiotics[1] and the Dietary Guidelines for Americans 2020-2025[2].

Inclusion criteria:

- Patients at risk of a dietary deficiency who could benefit from dietary supplement therapy due to diagnosis or history of one or more of the following conditions:
    - Alcoholism
    - Tobacco use
    - Substance use disorder
    - Poor-quality diets with low fruit and vegetable intake
    - Malabsorption
    - Bariatric surgery
    - Vegan diet
    - Those with nonhealing wounds

- On a medication known for drug-induced nutrient depletion including but not limited to: metformin, orlistat, beta agonists, corticosteroids, diuretics (loop or thiazide), proton pump inhibitors, H2 blockers, and statins
- Supplementation that satisfies the physiological needs or deficiencies for a specific disease state or condition
- Any other known or suspected dietary deficiency

- 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 would authorize pharmacists to initiate the dispensing of an over-the counter dietary supplement therapy using doses consistent with package labeling and clinical guidelines through professional judgement. Products would include only over-the-counter dietary supplements that:

- Have been manufactured in an FDA registered facility
- Contains no additional active ingredients that would require prescriptive permission
- Probiotic product/strain has approval of GRAS (generally recognized as safe) status with the Food and Drug Administration (FDA)
- Probiotics contain products/strains for the appropriate indications as identified by

the current World Gastroenterology Organisation Global Guidelines on Probiotics and Prebiotics
- Contains products/ingredients for appropriate indications as identified by the Dietary Guidelines for Americans 2020-2025[2] or the National Institute of Health (NIH) Office of Dietary Supplements[6].

PROCEDURES FOR INITIATING THERAPY

Dietary supplement therapy initiation would be individualized based on relevant medical and social history, patient preferences, and consideration of contraindications of therapy as outlined below.

- Relevant medical and social history
    - Past medical and social history
    - Current medications
    - Allergies and hypersensitivities
- Contraindications
    - Known hypersensitivities to any component of the formulation (as listed on the product label)
    - Pre-existing hypervitaminosis
    - Potential drug-drug interactions based on current medications

PROCEDURES FOR MONITORING AND CONTINUATION OF DISPENSING OVER-THE- COUNTER DIETARY SUPPLEMENTS

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 dispensing. 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 in initiation of therapies, including education, documentation, and notification, will be followed.

PATIENT EDUCATION REQUIREMENTS

Patient(s) receiving over-the-counter dietary supplement therapy under this protocol will receive education regarding:

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

DOCUMENTATION

Pharmacist(s) shall document, via prescription record, each person who receives any over-the-counter dietary supplement under this protocol, including:

- Documentation as required in 201 KAR 2:171 for the dispensing of prescription medications
- Documentation that the individual receiving the over-the-counter dietary supplement with the required education in accordance with this protocol and
- Documentation of the clinical indication for supplementation, product/strain dispensed, plan of care implemented, and follow-up monitoring and evaluation

NOTIFICATION

Pharmacist(s) shall ask all persons receiving over-the-counter dietary supplements under this protocol for the name and contact information of the individual's primary care provider. If a primary care physician is identified, the pharmacist(s) shall provide that physician with a summary of the encounter and notification of the supplement(s) dispensed under this protocol within two (2) business days. Any individual affirmatively stating that the individual does not have a primary care provider may still receive over-the-counter dietary supplement 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 nutrition supplementation under this protocol within 7 days of initiating dispensing.]

Resources used to develop 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]U.S. Department of Agriculture and U.S. Department of Health and Human Services. Dietary Guidelines for Americans, 2020-2025. 9th Edition. December 2020. Available at DietaryGuidelines.gov.

[3]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.

[4]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.

[5]National Center for Complementary and Integrative Health. Vitamins and minerals. U.S. Department of Health and Human Services. https://nccih.nih.gov/health/vitamins. Updated July 2023; Accessed April 2024

[6]The National Institutes of Health (NIH) Office of Dietary Supplements. Dietary Supplement Fact Sheets. https://ods.od.nih.gov/factsheets/list-all/

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: _____